表2.7.4.7-11　治験薬の貼付中止に至った有害事象の一覧（20試験・ロナセンテープ貼付期、Open-24週）
All Patients

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]07/ 3[redacted]/ M/ JPN	501	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 aggravation of schizophrenia	(80) ONGOING - Open-label treatment phase 80 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 5[redacted]/ F/ JPN	3	Nervous system disorders/神経系障害 Generalised tonic-clonic seizure/全身性強直性間代性発作 Tonic-clonic convulsions	(20) (21) 2 Double-blind treatment phase 40 mg/day	SEVERE/ POSSIBLE/ Y (Other medically important event)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 4[redacted]/ F/ JPN	3	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(3) ONGOING - Double-blind treatment phase 40 mg/day *	MODERATE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 7[redacted]/ F/ JPN	1	Nervous system disorders/神経系障害 Dyskinesia/ジスキネジア tongue dyskinesia	(4) ONGOING - Double-blind treatment phase 40 mg/day	MILD/ DEFINITE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
		2	Metabolism and nutrition disorders/代謝および栄養障害 Decreased appetite/食欲減退 anorexia aggravated	(10) ONGOING - Double-blind treatment phase 40 mg/day	MILD/ DEFINITE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
		3	Nervous system disorders/神経系障害 Akinesia/無動 akinesia	(10) ONGOING - Double-blind treatment phase 40 mg/day	MILD/ DEFINITE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
	1[redacted]04/ 2[redacted]/ F/ JPN	506 (1)	Investigations/臨床検査 Weight increased/体重増加 Weight gain	(30) ONGOING - Double-blind treatment phase 40 mg/day	MILD/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 6[redacted]/ F/ JPN	1	Psychiatric disorders/精神障害 Suicidal ideation/自殺念慮 suicidal ideation	(6) ONGOING - Double-blind treatment phase 40 mg/day	MODERATE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 4[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Aggravation of schizophrenia	(14) ONGOING - Double-blind treatment phase 40 mg/day *	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 5[redacted]/ M/ JPN	504	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of Schizophrenia	(128) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 2[redacted]/ F/ JPN	506	Psychiatric disorders/精神障害 Suicidal ideation/自殺念慮 suicidal idea	(179) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]08/ 6[redacted]/ M/ JPN	2	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of shizophrenia	(4) ONGOING - Double-blind treatment phase 40 mg/day	MODERATE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 5[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(9) (14) 6 Double-blind treatment phase 40 mg/day	SEVERE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
		2	Psychiatric disorders/精神障害 Sexually inappropriate behaviour/不適切な性的行動 Sexually inappropriate behaviour	(9) (14) 6 Double-blind treatment phase 40 mg/day	SEVERE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]07/ 3[redacted]/ M/ KOR	6	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of Schizophrenia	(26) (32) 7 Double-blind treatment phase 40 mg/day	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]01/ 3[redacted]/ F/ KOR	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of schizophrenia	(-2) ONGOING - Washout phase 0 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	3[redacted]11/ 3[redacted]/ M/ TWN	505	Psychiatric disorders/精神障害 Suicide attempt/自殺企図 Sucide attempt	(146) ONGOING - Open-label treatment phase 80 mg/day *	MILD/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	4[redacted]02/ 4[redacted]/ M/ MYS	3	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Exacerbation of psychosis	(17) ONGOING - Double-blind treatment phase 40 mg/day	MODERATE/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]03/ 3[redacted]/ F/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 worsening of psychosis	(10) ONGOING - Double-blind treatment phase 40 mg/day	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	4[redacted]08/ 3[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Worsening of psychosis	(12) (20) 9 Double-blind treatment phase 40 mg/day	MODERATE/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]15/ 4[redacted]/ F/ MYS	2	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 worsening of psychotic symptom	(9) (10) 2 Double-blind treatment phase 40 mg/day *	SEVERE/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]24/ 3[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Exacerbation of psychosis	(31) ONGOING - Double-blind treatment phase 40 mg/day	SEVERE/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
	4[redacted]28/ 5[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Worsening of psychosis	(3) (6) 4 Double-blind treatment phase 40 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
	4[redacted]37/ 1[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Worsening psychosis	(7) (13) 7 Double-blind treatment phase 40 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]05/ 4[redacted]/ F/ MYS	501	Musculoskeletal and connective tissue disorders/筋骨格系および結合組織障害 Limb discomfort/四肢不快感 FEELING HEAVINESS OF BOTH LEGS	(46) (55) 10 Open-label treatment phase 40 mg/day	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]10/ 2[redacted]/ F/ MYS	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 WORSENING SCHIZOPHRENIA	(21) ONGOING - Double-blind treatment phase 40 mg/day	SEVERE/ PROBABLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]03/ 3[redacted]/ M/ MYS	502	Psychiatric disorders/精神障害 Abnormal behaviour/異常行動 Worsening of Symptoms (Changing of behavior)	(110) (124) 15 Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]05/ 4[redacted]/ F/ MYS	512	Psychiatric disorders/精神障害 Aggression/攻撃性 Worsening of Symptom of aggressive behavior	(74) (75) 2 Open-label treatment phase 80 mg/day *	MODERATE/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	6[redacted]05/ 5[redacted]/ F/ CHN	501	Hepatobiliary disorders/肝胆道系障害 Hepatic function abnormal/肝機能異常 Abnormal liver function exacerbation	(134) ONGOING - Open-label treatment phase 40 mg/day	SEVERE/ PROBABLE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	7[redacted]06/ 3[redacted]/ M/ RUS	512	Psychiatric disorders/精神障害 Psychiatric symptom/精神症状 Worsening of psychic state	(175) (215) 41 Open-label treatment phase 80 mg/day	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	7[redacted]04/ 4[redacted]/ F/ RUS	502	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of schizophrenia	(53) (63) 11 Open-label treatment phase 60 mg/day	SEVERE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]03/ 3[redacted]/ M/ JPN	502	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(156) ONGOING - Open-label treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 5[redacted]/ F/ JPN	3	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site pruritus/適用部位そう痒感 itching(application site)	(-5) (24) 29 Washout phase 0 mg/day	MILD/ DEFINITE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 7[redacted]/ F/ JPN	501 (1)	Nervous system disorders/神経系障害 Akathisia/アカシジア akathisia	(8) ONGOING - Double-blind treatment phase 80 mg/day	SEVERE/ DEFINITE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
		502 (2)	Nervous system disorders/神経系障害 Parkinsonian gait/パーキンソン歩行 short-stepped gait	(16) ONGOING - Double-blind treatment phase 80 mg/day	MODERATE/ DEFINITE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
		503 (3)	Musculoskeletal and connective tissue disorders/筋骨格系および結合組織障害 Muscle rigidity/筋固縮 muscle rigidity	(16) (72) 57 Double-blind treatment phase 80 mg/day	MODERATE/ DEFINITE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]04/ 2[redacted]/ F/ JPN	501	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of Schizophrenia	(74) (92) 19 Open-label treatment phase 60 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]01/ 5[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(11) ONGOING - Double-blind treatment phase 80 mg/day	SEVERE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
	1[redacted]04/ 7[redacted]/ M/ JPN	503	Gastrointestinal disorders/胃腸障害 Nausea/悪心 Queasy	(58) (73) 16 Open-label treatment phase 40 mg/day	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]04/ 2[redacted]/ F/ JPN	505	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggrevated	(47) ONGOING - Open-label treatment phase 40 mg/day *	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	2[redacted]04/ 2[redacted]/ M/ KOR	1	Psychiatric disorders/精神障害 Agitation/激越 psychotic agitation	(25) ONGOING - Double-blind treatment phase 80 mg/day	MILD/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]01/ 3[redacted]/ M/ KOR	2	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of schizophrenia	(7) (40) 34 Double-blind treatment phase 80 mg/day	SEVERE/ DEFINITE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]04/ 5[redacted]/ F/ KOR	512	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of Schizoprenia	(87) ONGOING - Follow-up phase 80 mg/day *	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	4[redacted]08/ 2[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Suicide attempt/自殺企図 Suicidal attempt	(22) (31) 10 Double-blind treatment phase 80 mg/day *	SEVERE/ PROBABLE/ Y (Life threatening, Requires or prolongs hospitalization)	RECOVERED/RESOLVED WITH SEQUELAE/ DRUG WITHDRAWN
		2	Injury, poisoning and procedural complications/傷害、中毒および処置合併症 Pulmonary contusion/肺挫傷 BILATERAL LUNGS CONTUSSION	(22) (31) 10 Double-blind treatment phase 80 mg/day *	SEVERE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
		3	Injury, poisoning and procedural complications/傷害、中毒および処置合併症 Ankle fracture/足関節部骨折 LEFT CALCANEUM FRACTURE	(22) ONGOING - Double-blind treatment phase 80 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
		4	Injury, poisoning and procedural complications/傷害、中毒および処置合併症 Clavicle fracture/鎖骨骨折 RIGHT CLAVICLE FRACTURE	(22) ONGOING - Double-blind treatment phase 80 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
		5	Respiratory, thoracic and mediastinal disorders/呼吸器、胸郭および縦隔障害 Pulmonary embolism/肺塞栓症 TRO PULMONARY EMBOLISM	(26) (30) 5 Follow-up phase 80 mg/day *	SEVERE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]06/ 3[redacted]/ M/ MYS	1	Investigations/臨床検査 Blood creatine phosphokinase increased/血中クレアチンホスホキナーゼ増加 WORSENING OF CK ELEVATION	(4) (15) 12 Double-blind treatment phase 80 mg/day	MODERATE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
	4[redacted]16/ 2[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 WORSENING OF PSYCHOTIC SYMPTOMS	(11) (19) 9 Double-blind treatment phase 80 mg/day	MODERATE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]12/ 6[redacted]/ M/ MYS	1	Infections and infestations/感染症および寄生虫症 Pneumonia/肺炎 Pneumonia	(5) (12) 8 Double-blind treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Other medically important event)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]18/ 4[redacted]/ M/ MYS	1	Cardiac disorders/心臓障害 Acute myocardial infarction/急性心筋梗塞 Cardiogenic shock secondary to NSTEMI	(35) (36) 2 Double-blind treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Results in death, Requires or prolongs hospitalization)	FATAL/ DRUG WITHDRAWN
	4[redacted]25/ 4[redacted]/ M/ MYS	501	Gastrointestinal disorders/胃腸障害 Colitis/大腸炎 Colitis	(71) (71) 1 Open-label treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Results in death)	FATAL/ DRUG WITHDRAWN
	4[redacted]29/ 2[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 worsening of psychosis	(8) (16) 9 Double-blind treatment phase 80 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]01/ 3[redacted]/ F/ MYS	502	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of Schizophrenia	(99) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
	4[redacted]08/ 3[redacted]/ M/ MYS	1	Nervous system disorders/神経系障害 Guillain-Barre syndrome/ギラン・バレー症候群 GUILLAIN BARRE SYNDROME	(3) ONGOING - Double-blind treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Results in persistent or significant disability/incapacity)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]04/ 2[redacted]/ M/ MYS	502	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of schizophrenia symptoms	(134) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ PROBABLE/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	5[redacted]09/ 4[redacted]/ F/ PHL	501	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 relapse of symptoms/Schizophrenia	(119) ONGOING - Open-label treatment phase 40 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
	5[redacted]11/ 3[redacted]/ M/ PHL	2	Infections and infestations/感染症および寄生虫症 Pulmonary tuberculosis/肺結核 Pulmonary Tuberculosis	(41) ONGOING - Double-blind treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	5[redacted]01/ 2[redacted]/ F/ PHL	506	Psychiatric disorders/精神障害 Completed suicide/自殺既遂 Suicide attempt completed	(142) (142) 1 Open-label treatment phase 40 mg/day	SEVERE/ NOT RELATED/ Y (Results in death)	FATAL/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	7[redacted]02/ 5[redacted]/ F/ RUS	501	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of schizophrenia	(60) ONGOING - Follow-up phase 80 mg/day *	SEVERE/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	8[redacted]05/ 2[redacted]/ M/ UKR	501	Psychiatric disorders/精神障害 Psychiatric symptom/精神症状 worsening of psychiatric symptoms	(155) (161) 7 Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]02/ 4[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Catatonia/カタトニー Catatonia	(19) ONGOING - Double-blind treatment phase 0 mg/day	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 6[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(41) ONGOING - Double-blind treatment phase 0 mg/day	MODERATE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 2[redacted]/ F/ JPN	507	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsoring of schizophrenia	(89) (103) 15 Open-label treatment phase 80 mg/day *	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 7[redacted]/ F/ JPN	1	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site eczema/適用部位湿疹 eczema(application site)	(8) (21) 14 Double-blind treatment phase 0 mg/day	MILD/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 3[redacted]/ F/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 exacerbation of schizophrenic symptoms	(6) ONGOING - Double-blind treatment phase 0 mg/day *	MODERATE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 3[redacted]/ F/ JPN	2	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(10) ONGOING - Double-blind treatment phase 0 mg/day *	SEVERE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]06/ 5[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of Schizophrenia	(9) ONGOING - Double-blind treatment phase 0 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 5[redacted]/ F/ JPN	5	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(32) ONGOING - Double-blind treatment phase 0 mg/day	SEVERE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 3[redacted]/ M/ JPN	3	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of schizophrenia	(20) ONGOING - Double-blind treatment phase 0 mg/day	MILD/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]09/ 2[redacted]/ F/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of shizophrenia	(5) ONGOING - Double-blind treatment phase 0 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 6[redacted]/ F/ JPN	4	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 aggravation of Schizophrenia	(30) (32) 3 Double-blind treatment phase 0 mg/day	MODERATE/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]10/ 2[redacted]/ F/ KOR	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of schizophrenia	(1) ONGOING - Double-blind treatment phase 0 mg/day	SEVERE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	2[redacted]03/ 4[redacted]/ F/ KOR	2	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of schizophrenia	(8) ONGOING - Double-blind treatment phase 0 mg/day *	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]09/ 3[redacted]/ F/ MYS	506	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 WORSENING OF PSYCHOTIC SYMPTOMS	(161) (175) 15 Open-label treatment phase 60 mg/day	MILD/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]11/ 3[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 worsening of psychosis	(10) (18) 9 Double-blind treatment phase 0 mg/day	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]17/ 5[redacted]/ F/ MYS	501	Cardiac disorders/心臓障害 Bradycardia/徐脈 Bradycardiac	(29) (71) 43 Open-label treatment phase 80 mg/day	MILD/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]20/ 3[redacted]/ M/ MYS	502	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 worsening psychosis	(87) (98) 12 Open-label treatment phase 80 mg/day	MODERATE/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]36/ 4[redacted]/ F/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 worsening psychosis	(1) ONGOING - Double-blind treatment phase 0 mg/day	MODERATE/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	4[redacted]04/ 5[redacted]/ F/ MYS	502	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening Of Schizophrenia	(21) (50) 30 Open-label treatment phase 40 mg/day	SEVERE/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]07/ 3[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of schizophrenia	(10) (35) 26 Double-blind treatment phase 0 mg/day	SEVERE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]04/ 3[redacted]/ M/ MYS	508	Injury, poisoning and procedural complications/傷害、中毒および処置合併症 Toxicity to various agents/各種物質毒性 Methamphetamine Intoxication	(86) ONGOING - Open-label treatment phase 60 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	4[redacted]22/ 3[redacted]/ M/ MYS	505	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Relapse due to poor compliance	(155) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	4[redacted]01/ 6[redacted]/ M/ MYS	501	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 WORSENING OF CLINICAL SYMPTOM SCHIZOPHRENIA (PANSS SCORE FROM 93 TO 110)	(8) ONGOING - Open-label treatment phase 60 mg/day	MODERATE/ PROBABLE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	5[redacted]04/ 3[redacted]/ M/ PHL	3	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Worsening of psychotic symptoms related to Schizophrenia	(18) ONGOING - Double-blind treatment phase 0 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	5[redacted]04/ 2[redacted]/ M/ PHL	502	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Exacerbation of Psychosis Symptoms	(122) (167) 46 Open-label treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	6[redacted]04/ 6[redacted]/ M/ CHN	501	Gastrointestinal disorders/胃腸障害 Upper gastrointestinal haemorrhage/上部消化管出血 Upper gastrointestinal bleeding	(9) (25) 17 Open-label treatment phase 60 mg/day *	MODERATE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	7[redacted]02/ 3[redacted]/ F/ RUS	2	Nervous system disorders/神経系障害 Psychomotor hyperactivity/精神運動亢進 Psychomotor agitation	(7) (22) 16 Double-blind treatment phase 0 mg/day	SEVERE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
		3	Psychiatric disorders/精神障害 Negativism/拒絶症 Negativism	(7) (22) 16 Double-blind treatment phase 0 mg/day	SEVERE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	7[redacted]04/ 3[redacted]/ F/ RUS	503	Psychiatric disorders/精神障害 Psychiatric symptom/精神症状 Worsening of psychic state	(29) (42) 14 Open-label treatment phase 80 mg/day *	SEVERE/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	8[redacted]01/ 3[redacted]/ M/ UKR	501	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Exacerbation of psychosis	(8) (15) 8 Open-label treatment phase 40 mg/day *	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

Untreated

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]03/ 7[redacted]/ F/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(-) (-) - Washout phase -	MODERATE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 5[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of schizophrenia	(-) (-) - Washout phase -	SEVERE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

JPN = JAPAN, CHN = CHINA, KOR = KOREA, REPUBLIC OF, MYS = MALAYSIA, PHL = PHILIPPINES, RUS = RUSSIAN FEDERATION, TWN = TAIWAN, UKR = UKRAINE

Adverse events are coded by MedDRA version 19.1. In case that subjects didn't recieve an active treatment, study day (Day) is relative to the initial application in the double-blind treatment phase, but if subjects recieved an active treatment, study day (Day) is relative to the first day of receiving an active treatment regardless of treatment phase.

(#): No. in DB treatment (only in case of the ongoing AE from DB treatment) or No. in the Open-label phase (only in the case of worsened during the Open-label phase)

*, in the case that the dose at onset date is zero or missing, the most recent non-zero dose is displayed.

The data cut-off at Open-Week 24 was used.

Control No:<<l16-03-01-03-ae.sas, 2018-06-08T16:45:29>>

表2.7.4.7-12 治験薬の貼付中止に至った有害事象の一覧（40試験）
All Patients

Cohort 1

Site	Subject ID/ Age/ Sex/ Safety	#	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]03/ 2[redacted]/ F/ Y	5	Psychiatric disorders/精神障害 Suicidal ideation/自殺念慮 Suicidal ideaton	(176) (181) 6 PATCH TREATMENT P 60 mg/day	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 3[redacted]/ M/ Y	5	Psychiatric disorders/精神障害 Impulse-control disorder/衝動制御障害 Poor impulse control	(7) (14) 8 PATCH TREATMENT P 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 7[redacted]/ F/ Y	2	Injury, poisoning and procedural complications/傷害、中毒および処置合併症 Fracture/骨折 Fracture	(51) ONGOING - PATCH TREATMENT P 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
	1[redacted]07/ 2[redacted]/ F/ Y	2	Nervous system disorders/神経系障害 Judgement impaired/判断力低下 lack of judgment and insight	(274) (288) 15 PATCH TREATMENT P 40 mg/day	MILD/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	1[redacted]08/ 2[redacted]/ M/ Y	1	Hepatobiliary disorders/肝胆道系障害 Hepatic function abnormal/肝機能異常 Hepatic function disordor	(-28) ONGOING - TABLET TREATMENT T 8 mg/day	MILD/ DEFINITE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

Cohort 1

Site	Subject ID/ Age/ Sex/ Safety	#	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
	1[redacted]09/ 5[redacted]/ M/ Y	2	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Exacerbation of Schizophrenia	(35) ONGOING - PATCH TREATMENT P 60 mg/day	SEVERE/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]07/ 2[redacted]/ M/ Y	1	Musculoskeletal and connective tissue disorders/筋骨格系および結合組織障害 Muscle rigidity/筋固縮 Muscle rigidity	(181) ONGOING - PATCH TREATMENT P 80 mg/day	MILD/ DEFINITE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
		2	Nervous system disorders/神経系障害 Tremor/振戦 Tremor	(181) ONGOING - PATCH TREATMENT P 80 mg/day	MILD/ DEFINITE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
		3	Nervous system disorders/神経系障害 Dystonia/ジストニア Dystonia	(181) ONGOING - PATCH TREATMENT P 80 mg/day	MILD/ DEFINITE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
		4	Nervous system disorders/神経系障害 Dyskinesia/ジスキネジア Dyskinesia	(181) ONGOING - PATCH TREATMENT P 80 mg/day	MILD/ DEFINITE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 3[redacted]/ M/ Y	1	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site dermatitis/適用部位皮膚炎 dermatitis	(1) (7) 7 PATCH TREATMENT P 60 mg/day	MILD/ DEFINITE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

Cohort 1

Site	Subject ID/ Age/ Sex/ Safety	#	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]03/ 5[redacted]/ F/ Y	2	Nervous system disorders/神経系障害 Akathisia/アカシジア Akathisia aggravated	(111) ONGOING - PATCH TREATMENT P 40 mg/day	SEVERE/ PROBABLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 4[redacted]/ M/ Y	4	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(191) ONGOING - PATCH TREATMENT P 80 mg/day	MODERATE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]04/ 3[redacted]/ M/ Y	1	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site dermatitis/適用部位皮膚炎 Dermatitis	(10) ONGOING - PATCH TREATMENT P 80 mg/day	MODERATE/ DEFINITE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 3[redacted]/ F/ Y	6	Nervous system disorders/神経系障害 Tremor/振戦 tremor	(79) ONGOING - PATCH TREATMENT P 60 mg/day	MODERATE/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 3[redacted]/ M/ Y	1	Nervous system disorders/神経系障害 Tremor/振戦 Tremor	(-30) ONGOING - TABLET TREATMENT T 12 mg/day	MODERATE/ PROBABLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]05/ 5[redacted]/ F/ Y	2	Psychiatric disorders/精神障害 Depressive symptom/抑うつ症状 Depressive symptom	(23) ONGOING - PATCH TREATMENT P 40 mg/day	MILD/ POSSIBLE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN

Cohort 1

Site	Subject ID/ Age/ Sex/ Safety	#	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
	1[redacted]07/ 4[redacted]/ F/ Y	1	Psychiatric disorders/精神障害 Depression/うつ病 Depressive state	(85) ONGOING - PATCH TREATMENT P 40 mg/day	MILD/ POSSIBLE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
	1[redacted]09/ 7[redacted]/ F/ Y	1	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site erythema/適用部位紅斑 Erythemas	(25) ONGOING - PATCH TREATMENT P 80 mg/day *	MODERATE/ DEFINITE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 3[redacted]/ F/ Y	2	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(48) ONGOING - PATCH TREATMENT P 40 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 3[redacted]/ F/ Y	3	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site urticaria/適用部位蕁麻疹 Urticaria	(11) ONGOING - PATCH TREATMENT P 40 mg/day	MODERATE/ PROBABLE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN

Cohort 1 Not Treated

Site	Subject ID/ Age/ Sex/ Safety	#	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]04/ 4[redacted]/ F/ N	1	Psychiatric disorders/精神障害 Suicidal ideation/自殺念慮 suicidal ideation	(-) ONGOING - TABLET TREATMENT T 8 mg/day	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN

Cohort 2

Site	Subject ID/ Age/ Sex/ Safety	#	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]08/ 3[redacted]/ F/ Y	5	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site rash/適用部位発疹 Rash	(48) (78) 31 PATCH TREATMENT P 60 mg/day	MODERATE/ DEFINITE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
		6	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site exfoliation/適用部位皮膚剥脱 Desquamation	(48) (78) 31 PATCH TREATMENT P 60 mg/day	MODERATE/ DEFINITE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
		7	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site discolouration/適用部位変色 Pigmentation	(50) ONGOING - PATCH TREATMENT P 60 mg/day	MILD/ DEFINITE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 3[redacted]/ M/ Y	2	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of schizophrenia	(119) ONGOING - PATCH TREATMENT P 80 mg/day *	MODERATE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
	1[redacted]03/ 4[redacted]/ M/ Y	4	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of schizophrenia	(76) ONGOING - PATCH TREATMENT P 80 mg/day	MODERATE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN

Cohort 2

Site	Subject ID/ Age/ Sex/ Safety	#	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]21/ 5[redacted]/ F/ Y	2	Nervous system disorders/神経系障害 Akathisia/アカシジア Akathisia	(56) ONGOING - PATCH TREATMENT P 40 mg/day	MILD/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
		4	Nervous system disorders/神経系障害 Dyskinesia/ジスキネジア Dyskinesia	(103) ONGOING - PATCH TREATMENT P 40 mg/day	MILD/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]04/ 4[redacted]/ F/ Y	2	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site erythema/適用部位紅斑 Erythema	(40) (64) 25 PATCH TREATMENT P 80 mg/day	MILD/ DEFINITE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 4[redacted]/ F/ Y	1	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Chest discomfort/胸部不快感 chest distress	(3) (5) 3 PATCH TREATMENT P 40 mg/day	MILD/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]05/ 6[redacted]/ F/ Y	1	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Thirst/口渇 Thirst aggravated	(2) (18) 17 PATCH TREATMENT P 40 mg/day	MODERATE/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]13/ 3[redacted]/ F/ Y	6	Psychiatric disorders/精神障害 Suicide attempt/自殺企図 Attempted suicide	(117) (117) 1 PATCH TREATMENT P 40 mg/day	MILD/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

Cohort 2

Site	Subject ID/ Age/ Sex/ Safety	#	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]04/ 5[redacted]/ F/ Y	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(67) ONGOING - PATCH TREATMENT P 40 mg/day *	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]06/ 3[redacted]/ F/ Y	2	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site pruritus/適用部位そう痒感 Itching	(22) (229) 208 PATCH TREATMENT P 40 mg/day	MODERATE/ DEFINITE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]04/ 5[redacted]/ F/ Y	2	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(314) ONGOING - PATCH TREATMENT P 80 mg/day	SEVERE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 6[redacted]/ M/ Y	3	Investigations/臨床検査 Blood creatine phosphokinase increased/血中クレアチンホスホキナーゼ増加 CPK increased	(111) (118) 8 PATCH TREATMENT P 40 mg/day	MILD/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

Adverse events are coded by MedDRA version 19.1. Study day (Day) is relative to the initial application date of the DSP-5423P treatment phase. A day before Day 1 is Day -1. Duration of adverse event is end date - start date + 1. T, tablet formulation; P, patch formulation.

*, in the case that the dose at onset date is zero or missing, the most recent non-zero dose is displayed.

Control No:<<l16-02-07-04-ae.sas, 2017-11-20T12:42:31>>

表2.7.4.7-13　日本人集団での人口統計学的特性及びその他の特性（20試験・ロナセンテープ貼付期、Open-24週）
DSP-5423P Dosed Population

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
Sex, n (%)					
n	27	55	57	112	139
Male	16 (59.3)	26 (47.3)	29 (50.9)	55 (49.1)	71 (51.1)
Female	11 (40.7)	29 (52.7)	28 (49.1)	57 (50.9)	68 (48.9)
Age (years)					
n	27	55	57	112	139
Mean (SD)	51.6 (14.90)	47.5 (16.03)	48.0 (17.18)	47.8 (16.55)	48.5 (16.26)
Median	53.0	49.0	52.0	49.5	50.0
Min, Max	20, 73	20, 79	22, 81	20, 81	20, 81
Age (years), n (%)					
n	27	55	57	112	139
<65	20 (74.1)	45 (81.8)	46 (80.7)	91 (81.3)	111 (79.9)
>=65	7 (25.9)	10 (18.2)	11 (19.3)	21 (18.8)	28 (20.1)
Race, n (%)					
n	27	55	57	112	139
Asian	27 (100.0)	55 (100.0)	57 (100.0)	112 (100.0)	139 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	27	55	57	112	139
Not Hispanic or Latino	27 (100.0)	55 (100.0)	57 (100.0)	112 (100.0)	139 (100.0)
Country, n (%)					
n	27	55	57	112	139

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
Japan	27 (100.0)	55 (100.0)	57 (100.0)	112 (100.0)	139 (100.0)
China	0	0	0	0	0
Korea	0	0	0	0	0
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	27	55	57	112	139
Mean (SD)	164.08 (10.428)	161.02 (9.431)	160.78 (10.830)	160.90 (10.122)	161.52 (10.222)
Median	163.80	162.10	160.00	160.55	161.50
Min, Max	143.6, 182.0	138.0, 184.2	130.5, 182.0	130.5, 184.2	130.5, 184.2
Weight (kg)					
n	27	55	57	112	139
Mean (SD)	62.63 (15.590)	58.45 (12.770)	56.54 (13.849)	57.48 (13.305)	58.48 (13.870)
Median	61.10	56.20	54.20	56.10	57.00
Min, Max	39.6, 109.9	35.8, 87.9	31.2, 93.6	31.2, 93.6	31.2, 109.9
BMI (kg/m^2)					
n	27	55	57	112	139
Mean (SD)	23.19 (4.895)	22.51 (4.439)	21.67 (3.924)	22.08 (4.187)	22.30 (4.337)
Median	22.32	21.69	20.47	20.92	21.21
Min, Max	17.1, 33.9	15.5, 36.1	13.9, 31.1	13.9, 36.1	13.9, 36.1
Any concomitant diseases, n (%)					
n	27	55	57	112	139
Yes	24 (88.9)	47 (85.5)	52 (91.2)	99 (88.4)	123 (88.5)

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
No	3 (11.1)	8 (14.5)	5 (8.8)	13 (11.6)	16 (11.5)
Hospitalization status at informed consent, n (%)					
n	27	55	57	112	139
Inpatient	23 (85.2)	48 (87.3)	55 (96.5)	103 (92.0)	126 (90.6)
Within 3 months (90 days)	19 (70.4)	33 (60.0)	43 (75.4)	76 (67.9)	95 (68.3)
Over 3 months	4 (14.8)	15 (27.3)	12 (21.1)	27 (24.1)	31 (22.3)
Unknown	0	0	0	0	0
Outpatient	4 (14.8)	7 (12.7)	2 (3.5)	9 (8.0)	13 (9.4)

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Sex, n (%)					
n	8	9	10	19	27
Male	7 (87.5)	1 (11.1)	2 (20.0)	3 (15.8)	10 (37.0)
Female	1 (12.5)	8 (88.9)	8 (80.0)	16 (84.2)	17 (63.0)
Age (years)					
n	8	9	10	19	27
Mean (SD)	47.6 (17.61)	41.8 (15.21)	36.2 (13.73)	38.8 (14.33)	41.4 (15.57)
Median	51.0	39.0	32.0	36.0	39.0
Min, Max	22, 68	24, 62	20, 60	20, 62	20, 68
Age (years), n (%)					
n	8	9	10	19	27
<65	7 (87.5)	9 (100.0)	10 (100.0)	19 (100.0)	26 (96.3)
>=65	1 (12.5)	0	0	0	1 (3.7)
Race, n (%)					
n	8	9	10	19	27
Asian	8 (100.0)	9 (100.0)	10 (100.0)	19 (100.0)	27 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	8	9	10	19	27
Not Hispanic or Latino	8 (100.0)	9 (100.0)	10 (100.0)	19 (100.0)	27 (100.0)
Country, n (%)					
n	8	9	10	19	27
Japan	0	0	0	0	0
China	8 (100.0)	9 (100.0)	10 (100.0)	19 (100.0)	27 (100.0)
Korea	0	0	0	0	0

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	8	9	10	19	27
Mean (SD)	167.19 (6.708)	161.39 (2.759)	164.15 (8.199)	162.84 (6.245)	164.13 (6.573)
Median	166.50	160.00	162.25	160.50	163.50
Min, Max	155.0, 177.0	158.5, 166.0	154.0, 182.0	154.0, 182.0	154.0, 182.0
Weight (kg)					
n	8	9	10	19	27
Mean (SD)	68.93 (17.824)	64.67 (14.499)	67.39 (18.517)	66.10 (16.335)	66.94 (16.492)
Median	61.85	60.00	64.50	60.00	61.00
Min, Max	48.5, 103.0	50.0, 91.5	44.5, 96.5	44.5, 96.5	44.5, 103.0
BMI (kg/m^2)					
n	8	9	10	19	27
Mean (SD)	24.56 (5.483)	24.84 (5.645)	25.02 (6.721)	24.94 (6.063)	24.82 (5.794)
Median	22.85	23.44	23.72	23.44	22.88
Min, Max	17.2, 32.9	18.1, 36.2	17.8, 35.3	17.8, 36.2	17.2, 36.2
Any concomitant diseases, n (%)					
n	8	9	10	19	27
Yes	6 (75.0)	7 (77.8)	5 (50.0)	12 (63.2)	18 (66.7)
No	2 (25.0)	2 (22.2)	5 (50.0)	7 (36.8)	9 (33.3)
Hospitalization status at informed consent, n (%)					

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
n	8	9	10	19	27
Inpatient	8 (100.0)	9 (100.0)	10 (100.0)	19 (100.0)	27 (100.0)
Within 3 months (90 days)	6 (75.0)	7 (77.8)	8 (80.0)	15 (78.9)	21 (77.8)
Over 3 months	2 (25.0)	2 (22.2)	2 (20.0)	4 (21.1)	6 (22.2)
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Sex, n (%)					
n	3	7	7	14	17
Male	1 (33.3)	4 (57.1)	4 (57.1)	8 (57.1)	9 (52.9)
Female	2 (66.7)	3 (42.9)	3 (42.9)	6 (42.9)	8 (47.1)
Age (years)					
n	3	7	7	14	17
Mean (SD)	51.3 (2.08)	39.7 (11.80)	40.4 (10.63)	40.1 (10.80)	42.1 (10.71)
Median	52.0	36.0	43.0	36.5	43.0
Min, Max	49, 53	27, 64	23, 56	23, 64	23, 64
Age (years), n (%)					
n	3	7	7	14	17
<65	3 (100.0)	7 (100.0)	7 (100.0)	14 (100.0)	17 (100.0)
>=65	0	0	0	0	0
Race, n (%)					
n	3	7	7	14	17
Asian	3 (100.0)	7 (100.0)	7 (100.0)	14 (100.0)	17 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	3	7	7	14	17
Not Hispanic or Latino	3 (100.0)	7 (100.0)	7 (100.0)	14 (100.0)	17 (100.0)
Country, n (%)					
n	3	7	7	14	17
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	3 (100.0)	7 (100.0)	7 (100.0)	14 (100.0)	17 (100.0)

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	3	7	7	14	17
Mean (SD)	155.30 (7.973)	163.51 (10.425)	168.50 (10.162)	166.01 (10.223)	164.12 (10.515)
Median	156.00	158.50	169.60	166.55	162.90
Min, Max	147.0, 162.9	152.0, 181.5	154.9, 180.5	152.0, 181.5	147.0, 181.5
Weight (kg)					
n	3	7	7	14	17
Mean (SD)	53.97 (7.900)	59.83 (21.166)	64.71 (8.051)	62.27 (15.592)	60.81 (14.696)
Median	52.20	48.20	66.80	61.65	61.60
Min, Max	47.1, 62.6	41.8, 96.8	51.1, 73.9	41.8, 96.8	41.8, 96.8
BMI (kg/m^2)					
n	3	7	7	14	17
Mean (SD)	22.37 (2.625)	21.83 (4.892)	22.78 (2.062)	22.31 (3.640)	22.32 (3.410)
Median	23.59	20.43	22.01	21.54	21.54
Min, Max	19.4, 24.2	16.6, 29.4	20.7, 25.7	16.6, 29.4	16.6, 29.4
Any concomitant diseases, n (%)					
n	3	7	7	14	17
Yes	3 (100.0)	6 (85.7)	5 (71.4)	11 (78.6)	14 (82.4)
No	0	1 (14.3)	2 (28.6)	3 (21.4)	3 (17.6)
Hospitalization status at informed consent, n (%)					

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
n	3	7	7	14	17
Inpatient	3 (100.0)	7 (100.0)	6 (85.7)	13 (92.9)	16 (94.1)
Within 3 months (90 days)	2 (66.7)	7 (100.0)	5 (71.4)	12 (85.7)	14 (82.4)
Over 3 months	0	0	1 (14.3)	1 (7.1)	1 (5.9)
Unknown	1 (33.3)	0	0	0	1 (5.9)
Outpatient	0	0	1 (14.3)	1 (7.1)	1 (5.9)

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Sex, n (%)					
n	43	58	54	112	155
Male	29 (67.4)	41 (70.7)	41 (75.9)	82 (73.2)	111 (71.6)
Female	14 (32.6)	17 (29.3)	13 (24.1)	30 (26.8)	44 (28.4)
Age (years)					
n	43	58	54	112	155
Mean (SD)	40.4 (9.92)	36.9 (10.57)	35.9 (11.95)	36.4 (11.22)	37.5 (10.99)
Median	38.0	38.0	35.0	35.5	37.0
Min, Max	22, 62	19, 62	18, 69	18, 69	18, 69
Age (years), n (%)					
n	43	58	54	112	155
<65	43 (100.0)	58 (100.0)	53 (98.1)	111 (99.1)	154 (99.4)
>=65	0	0	1 (1.9)	1 (0.9)	1 (0.6)
Race, n (%)					
n	43	58	54	112	155
Asian	43 (100.0)	58 (100.0)	54 (100.0)	112 (100.0)	155 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	43	58	54	112	155
Not Hispanic or Latino	43 (100.0)	58 (100.0)	54 (100.0)	112 (100.0)	155 (100.0)
Country, n (%)					
n	43	58	54	112	155
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Malaysia	43 (100.0)	58 (100.0)	54 (100.0)	112 (100.0)	155 (100.0)
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	43	58	54	112	155
Mean (SD)	163.78 (9.293)	163.27 (9.886)	163.85 (9.204)	163.55 (9.525)	163.61 (9.432)
Median	164.00	164.00	165.25	164.75	164.30
Min, Max	148.0, 186.0	125.0, 185.0	136.0, 180.0	125.0, 185.0	125.0, 186.0
Weight (kg)					
n	43	58	54	112	155
Mean (SD)	64.63 (13.887)	63.81 (15.358)	63.98 (14.815)	63.89 (15.031)	64.10 (14.682)
Median	63.00	60.00	61.25	60.45	61.00
Min, Max	44.9, 122.0	41.0, 118.0	27.9, 103.0	27.9, 118.0	27.9, 122.0
BMI (kg/m^2)					
n	43	58	54	112	155
Mean (SD)	24.19 (5.236)	24.10 (6.230)	23.83 (5.179)	23.97 (5.724)	24.03 (5.577)
Median	23.18	23.23	23.18	23.22	23.19
Min, Max	16.9, 43.7	14.5, 46.8	13.6, 35.6	13.6, 46.8	13.6, 46.8
Any concomitant diseases, n (%)					
n	43	58	54	112	155
Yes	16 (37.2)	25 (43.1)	22 (40.7)	47 (42.0)	63 (40.6)
No	27 (62.8)	33 (56.9)	32 (59.3)	65 (58.0)	92 (59.4)
Hospitalization status at informed consent, n (%)					

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
n	43	58	54	112	155
Inpatient	43 (100.0)	58 (100.0)	54 (100.0)	112 (100.0)	155 (100.0)
Within 3 months (90 days)	42 (97.7)	56 (96.6)	54 (100.0)	110 (98.2)	152 (98.1)
Over 3 months	1 (2.3)	2 (3.4)	0	2 (1.8)	3 (1.9)
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Sex, n (%)					
n	22	22	22	44	66
Male	15 (68.2)	19 (86.4)	16 (72.7)	35 (79.5)	50 (75.8)
Female	7 (31.8)	3 (13.6)	6 (27.3)	9 (20.5)	16 (24.2)
Age (years)					
n	22	22	22	44	66
Mean (SD)	33.6 (9.94)	32.7 (9.24)	32.4 (9.07)	32.5 (9.05)	32.9 (9.29)
Median	33.0	33.0	31.0	32.5	32.5
Min, Max	19, 56	20, 57	20, 55	20, 57	19, 57
Age (years), n (%)					
n	22	22	22	44	66
<65	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
>=65	0	0	0	0	0
Race, n (%)					
n	22	22	22	44	66
Asian	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	22	22	22	44	66
Not Hispanic or Latino	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
Country, n (%)					
n	22	22	22	44	66
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Malaysia	0	0	0	0	0
Philippines	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	22	22	22	44	66
Mean (SD)	158.75 (8.570)	161.68 (6.170)	161.85 (7.570)	161.77 (6.825)	160.76 (7.523)
Median	158.50	161.80	164.75	162.80	161.00
Min, Max	137.0, 172.7	147.3, 175.0	145.0, 172.0	145.0, 175.0	137.0, 175.0
Weight (kg)					
n	22	22	22	44	66
Mean (SD)	58.92 (10.267)	58.77 (9.044)	59.60 (7.628)	59.18 (8.279)	59.10 (8.911)
Median	56.45	56.95	58.45	58.20	57.35
Min, Max	47.5, 90.2	42.8, 79.0	48.0, 74.7	42.8, 79.0	42.8, 90.2
BMI (kg/m^2)					
n	22	22	22	44	66
Mean (SD)	23.43 (4.038)	22.46 (2.984)	22.76 (2.556)	22.61 (2.750)	22.89 (3.228)
Median	22.56	22.22	22.89	22.43	22.51
Min, Max	19.1, 37.1	15.7, 27.9	18.8, 26.9	15.7, 27.9	15.7, 37.1
Any concomitant diseases, n (%)					
n	22	22	22	44	66
Yes	3 (13.6)	2 (9.1)	4 (18.2)	6 (13.6)	9 (13.6)
No	19 (86.4)	20 (90.9)	18 (81.8)	38 (86.4)	57 (86.4)
Hospitalization status at informed consent, n (%)					

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
n	22	22	22	44	66
Inpatient	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
Within 3 months (90 days)	21 (95.5)	21 (95.5)	22 (100.0)	43 (97.7)	64 (97.0)
Over 3 months	1 (4.5)	1 (4.5)	0	1 (2.3)	2 (3.0)
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Sex, n (%)					
n	10	13	12	25	35
Male	5 (50.0)	6 (46.2)	5 (41.7)	11 (44.0)	16 (45.7)
Female	5 (50.0)	7 (53.8)	7 (58.3)	14 (56.0)	19 (54.3)
Age (years)					
n	10	13	12	25	35
Mean (SD)	33.7 (12.12)	39.5 (15.20)	42.8 (10.66)	41.0 (13.05)	38.9 (13.06)
Median	32.0	37.0	44.0	40.0	37.0
Min, Max	18, 54	18, 68	23, 59	18, 68	18, 68
Age (years), n (%)					
n	10	13	12	25	35
<65	10 (100.0)	12 (92.3)	12 (100.0)	24 (96.0)	34 (97.1)
>=65	0	1 (7.7)	0	1 (4.0)	1 (2.9)
Race, n (%)					
n	10	13	12	25	35
Asian	0	1 (7.7)	0	1 (4.0)	1 (2.9)
White	10 (100.0)	12 (92.3)	12 (100.0)	24 (96.0)	34 (97.1)
Ethnicity, n (%)					
n	10	13	12	25	35
Not Hispanic or Latino	10 (100.0)	13 (100.0)	12 (100.0)	25 (100.0)	35 (100.0)
Country, n (%)					
n	10	13	12	25	35
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	10 (100.0)	13 (100.0)	12 (100.0)	25 (100.0)	35 (100.0)
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	10	13	12	25	35
Mean (SD)	173.80 (13.054)	166.12 (11.832)	165.17 (8.288)	165.66 (10.086)	167.99 (11.438)
Median	173.50	166.00	166.50	166.00	168.00
Min, Max	150.0, 200.0	140.0, 181.0	145.0, 174.0	140.0, 181.0	140.0, 200.0
Weight (kg)					
n	10	13	12	25	35
Mean (SD)	88.01 (31.086)	66.85 (14.129)	70.41 (17.985)	68.56 (15.854)	74.11 (22.644)
Median	77.70	65.70	67.65	65.70	69.70
Min, Max	53.0, 149.8	48.1, 86.1	50.2, 118.7	48.1, 118.7	48.1, 149.8
BMI (kg/m^2)					
n	10	13	12	25	35
Mean (SD)	29.02 (9.266)	24.27 (4.647)	26.03 (7.402)	25.11 (6.059)	26.23 (7.201)
Median	26.39	26.01	24.20	24.44	24.44
Min, Max	19.7, 44.2	16.6, 31.5	16.8, 45.8	16.6, 45.8	16.6, 45.8
Any concomitant diseases, n (%)					
n	10	13	12	25	35
Yes	7 (70.0)	8 (61.5)	9 (75.0)	17 (68.0)	24 (68.6)
No	3 (30.0)	5 (38.5)	3 (25.0)	8 (32.0)	11 (31.4)
Hospitalization status at informed consent, n (%)					

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
n	10	13	12	25	35
Inpatient	10 (100.0)	13 (100.0)	12 (100.0)	25 (100.0)	35 (100.0)
Within 3 months (90 days)	10 (100.0)	13 (100.0)	12 (100.0)	25 (100.0)	35 (100.0)
Over 3 months	0	0	0	0	0
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Sex, n (%)					
n	5	15	17	32	37
Male	3 (60.0)	8 (53.3)	8 (47.1)	16 (50.0)	19 (51.4)
Female	2 (40.0)	7 (46.7)	9 (52.9)	16 (50.0)	18 (48.6)
Age (years)					
n	5	15	17	32	37
Mean (SD)	42.0 (13.29)	39.1 (7.17)	43.4 (9.97)	41.4 (8.89)	41.5 (9.37)
Median	42.0	39.0	43.0	40.5	41.0
Min, Max	23, 58	25, 49	24, 61	24, 61	23, 61
Age (years), n (%)					
n	5	15	17	32	37
<65	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
>=65	0	0	0	0	0
Race, n (%)					
n	5	15	17	32	37
Asian	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	5	15	17	32	37
Not Hispanic or Latino	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
Country, n (%)					
n	5	15	17	32	37
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
Ukraine	0	0	0	0	0
Height (cm)					
n	5	15	17	32	37
Mean (SD)	159.70 (8.628)	165.29 (8.637)	162.95 (9.465)	164.04 (9.019)	163.46 (8.976)
Median	157.00	167.00	162.00	163.85	163.00
Min, Max	151.0, 173.0	148.0, 178.0	149.0, 180.0	148.0, 180.0	148.0, 180.0
Weight (kg)					
n	5	15	17	32	37
Mean (SD)	62.90 (15.892)	66.83 (15.405)	65.38 (14.400)	66.06 (14.654)	65.64 (14.635)
Median	70.00	67.00	67.50	67.25	67.50
Min, Max	42.0, 76.5	46.0, 92.0	43.2, 92.0	43.2, 92.0	42.0, 92.0
BMI (kg/m^2)					
n	5	15	17	32	37
Mean (SD)	24.42 (4.675)	24.18 (3.617)	24.60 (5.116)	24.40 (4.412)	24.41 (4.380)
Median	25.56	24.05	23.49	23.77	24.05
Min, Max	17.6, 28.6	18.9, 31.4	18.4, 37.3	18.4, 37.3	17.6, 37.3
Any concomitant diseases, n (%)					
n	5	15	17	32	37
Yes	3 (60.0)	13 (86.7)	12 (70.6)	25 (78.1)	28 (75.7)
No	2 (40.0)	2 (13.3)	5 (29.4)	7 (21.9)	9 (24.3)
Hospitalization status at informed consent, n (%)					

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
n	5	15	17	32	37
Inpatient	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
Within 3 months (90 days)	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
Over 3 months	0	0	0	0	0
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Sex, n (%)					
n	13	17	15	32	45
Male	9 (69.2)	11 (64.7)	10 (66.7)	21 (65.6)	30 (66.7)
Female	4 (30.8)	6 (35.3)	5 (33.3)	11 (34.4)	15 (33.3)
Age (years)					
n	13	17	15	32	45
Mean (SD)	39.2 (7.69)	44.7 (9.14)	39.3 (12.60)	42.2 (11.07)	41.3 (10.21)
Median	37.0	45.0	37.0	43.0	42.0
Min, Max	26, 49	26, 60	20, 64	20, 64	20, 64
Age (years), n (%)					
n	13	17	15	32	45
<65	13 (100.0)	17 (100.0)	15 (100.0)	32 (100.0)	45 (100.0)
>=65	0	0	0	0	0
Race, n (%)					
n	13	17	15	32	45
Asian	0	0	0	0	0
White	13 (100.0)	17 (100.0)	15 (100.0)	32 (100.0)	45 (100.0)
Ethnicity, n (%)					
n	13	17	15	32	45
Not Hispanic or Latino	13 (100.0)	17 (100.0)	15 (100.0)	32 (100.0)	45 (100.0)
Country, n (%)					
n	13	17	15	32	45
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	13 (100.0)	17 (100.0)	15 (100.0)	32 (100.0)	45 (100.0)
Height (cm)					
n	13	17	15	32	45
Mean (SD)	171.15 (8.830)	172.74 (6.982)	170.53 (5.963)	171.70 (6.517)	171.54 (7.159)
Median	174.00	173.00	168.00	172.00	173.00
Min, Max	155.0, 184.0	163.5, 183.0	162.0, 183.0	162.0, 183.0	155.0, 184.0
Weight (kg)					
n	13	17	15	32	45
Mean (SD)	75.36 (9.774)	75.62 (13.790)	72.66 (11.540)	74.23 (12.670)	74.56 (11.808)
Median	73.00	70.50	68.80	70.00	71.00
Min, Max	61.3, 94.0	55.5, 112.0	54.3, 91.4	54.3, 112.0	54.3, 112.0
BMI (kg/m^2)					
n	13	17	15	32	45
Mean (SD)	25.69 (2.399)	25.47 (5.167)	24.99 (3.717)	25.25 (4.481)	25.37 (3.970)
Median	25.51	23.01	24.45	23.63	24.49
Min, Max	21.8, 30.4	19.6, 37.9	17.1, 31.2	17.1, 37.9	17.1, 37.9
Any concomitant diseases, n (%)					
n	13	17	15	32	45
Yes	4 (30.8)	4 (23.5)	3 (20.0)	7 (21.9)	11 (24.4)
No	9 (69.2)	13 (76.5)	12 (80.0)	25 (78.1)	34 (75.6)
Hospitalization status at informed consent, n (%)					

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
n	13	17	15	32	45
Inpatient	13 (100.0)	16 (94.1)	13 (86.7)	29 (90.6)	42 (93.3)
Within 3 months (90 days)	13 (100.0)	16 (94.1)	13 (86.7)	29 (90.6)	42 (93.3)
Over 3 months	0	0	0	0	0
Unknown	0	0	0	0	0
Outpatient	0	1 (5.9)	2 (13.3)	3 (9.4)	3 (6.7)

The denominator of percentages is the number of subjects in analysis population of subgroup. The data cut-off at Open-Week 24 was used.
Control No:<<t14-01-04-06-01-dm.sas, 2018-06-07T13:05:08>>

表2.7.4.7-14　日本人集団での疾患データ（20試験・ロナセンテープ貼付期、Open-24週）
DSP-5423P Dosed Population

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
Number of episodes of schizophrenia					
n	24	40	48	88	112
Mean (SD)	3.7 (1.52)	3.3 (1.43)	3.9 (1.34)	3.6 (1.41)	3.6 (1.43)
Median	4.5	3.0	5.0	4.0	4.0
Min, Max	1, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	27	55	57	112	139
1	3 (11.1)	4 (7.3)	3 (5.3)	7 (6.3)	10 (7.2)
2	3 (11.1)	11 (20.0)	6 (10.5)	17 (15.2)	20 (14.4)
3	4 (14.8)	9 (16.4)	9 (15.8)	18 (16.1)	22 (15.8)
4	2 (7.4)	3 (5.5)	5 (8.8)	8 (7.1)	10 (7.2)
5 or more	12 (44.4)	13 (23.6)	25 (43.9)	38 (33.9)	50 (36.0)
Unknown	3 (11.1)	15 (27.3)	9 (15.8)	24 (21.4)	27 (19.4)
Age at the first onset of schizophrenia (years)					
n	27	53	56	109	136
Mean (SD)	29.6 (11.28)	29.5 (12.97)	28.3 (11.87)	28.9 (12.38)	29.1 (12.13)
Median	28.0	25.0	25.0	25.0	25.5
Min, Max	12, 58	12, 67	13, 60	12, 67	12, 67
Age at the first onset of schizophrenia (years), n (%)					
n	27	55	57	112	139
19 or less	6 (22.2)	12 (21.8)	16 (28.1)	28 (25.0)	34 (24.5)
20 to 29	8 (29.6)	22 (40.0)	18 (31.6)	40 (35.7)	48 (34.5)
30 to 39	8 (29.6)	7 (12.7)	11 (19.3)	18 (16.1)	26 (18.7)
40 to 49	4 (14.8)	7 (12.7)	8 (14.0)	15 (13.4)	19 (13.7)

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
50 or more	1 (3.7)	5 (9.1)	3 (5.3)	8 (7.1)	9 (6.5)
Unknown	0	2 (3.6)	1 (1.8)	3 (2.7)	3 (2.2)
Duration of illness (years)					
n	27	53	56	109	136
Mean (SD)	21.84 (16.942)	17.97 (14.593)	19.58 (15.449)	18.79 (14.991)	19.40 (15.380)
Median	22.88	13.68	15.82	15.35	15.39
Min, Max	0.1, 47.8	0.3, 55.2	0.7, 50.6	0.3, 55.2	0.1, 55.2
Duration of illness (years), n (%)					
n	27	55	57	112	139
<1	2 (7.4)	4 (7.3)	1 (1.8)	5 (4.5)	7 (5.0)
>=1 to <5	4 (14.8)	9 (16.4)	8 (14.0)	17 (15.2)	21 (15.1)
>=5 to <10	4 (14.8)	5 (9.1)	13 (22.8)	18 (16.1)	22 (15.8)
>=10 to <20	3 (11.1)	15 (27.3)	11 (19.3)	26 (23.2)	29 (20.9)
>=20 to <30	5 (18.5)	9 (16.4)	10 (17.5)	19 (17.0)	24 (17.3)
>=30	9 (33.3)	11 (20.0)	13 (22.8)	24 (21.4)	33 (23.7)
Unknown	0	2 (3.6)	1 (1.8)	3 (2.7)	3 (2.2)
Duration of current episode (months)					
n	27	55	57	112	139
Mean (SD)	12.71 (58.388)	8.38 (46.869)	9.27 (59.028)	8.84 (53.167)	9.59 (54.021)
Median	1.18	1.35	1.15	1.22	1.22
Min, Max	0.3, 304.8	0.0, 348.9	0.2, 447.0	0.0, 447.0	0.0, 447.0
Baseline PANSS total score					
n	27	55	57	112	139
Mean (SD)	102.3 (16.99)	102.7 (16.85)	104.5 (15.45)	103.6 (16.11)	103.4 (16.23)
Median	99.0	101.0	101.0	101.0	101.0
Min, Max	80, 141	80, 157	83, 155	80, 157	80, 157

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
PANSS composite subscale at baseline, n (%)					
n	27	55	57	112	139
Positive subscale score>Negative subscale score	9 (33.3)	23 (41.8)	21 (36.8)	44 (39.3)	53 (38.1)
Positive subscale score=Negative subscale score	1 (3.7)	2 (3.6)	5 (8.8)	7 (6.3)	8 (5.8)
Positive subscale score<Negative subscale score	17 (63.0)	30 (54.5)	31 (54.4)	61 (54.5)	78 (56.1)
Baseline PANSS total score, n (%)					
n	27	55	57	112	139
<100	14 (51.9)	27 (49.1)	25 (43.9)	52 (46.4)	66 (47.5)
>=100 to <120	9 (33.3)	19 (34.5)	24 (42.1)	43 (38.4)	52 (37.4)
>=120	4 (14.8)	9 (16.4)	8 (14.0)	17 (15.2)	21 (15.1)
Baseline CGI-S score					
n	27	55	57	112	139
Mean (SD)	4.56 (0.751)	4.64 (0.825)	4.77 (0.887)	4.71 (0.856)	4.68 (0.836)
Median	4.00	4.00	5.00	5.00	4.00
Min, Max	4, 6	3, 7	3, 7	3, 7	3, 7
Baseline CGI-S score, n (%)					
n	27	55	57	112	139
1	0	0	0	0	0
2	0	0	0	0	0
3	0	1 (1.8)	1 (1.8)	2 (1.8)	2 (1.4)
4	16 (59.3)	28 (50.9)	25 (43.9)	53 (47.3)	69 (49.6)
5	7 (25.9)	17 (30.9)	19 (33.3)	36 (32.1)	43 (30.9)
6	4 (14.8)	8 (14.5)	10 (17.5)	18 (16.1)	22 (15.8)
7	0	1 (1.8)	2 (3.5)	3 (2.7)	3 (2.2)
Baseline DIEPSS total score (excluding overall severity)					

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
n	27	55	56	111	138
Mean (SD)	1.7 (2.88)	1.6 (3.00)	1.9 (3.54)	1.8 (3.27)	1.8 (3.19)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 10	0, 14	0, 14	0, 14	0, 14

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Number of episodes of schizophrenia					
n	8	9	10	19	27
Mean (SD)	3.8 (1.58)	3.6 (1.59)	2.7 (1.49)	3.1 (1.56)	3.3 (1.56)
Median	4.5	4.0	2.0	3.0	3.0
Min, Max	1, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	8	9	10	19	27
1	1 (12.5)	1 (11.1)	2 (20.0)	3 (15.8)	4 (14.8)
2	1 (12.5)	2 (22.2)	4 (40.0)	6 (31.6)	7 (25.9)
3	1 (12.5)	1 (11.1)	1 (10.0)	2 (10.5)	3 (11.1)
4	1 (12.5)	1 (11.1)	1 (10.0)	2 (10.5)	3 (11.1)
5 or more	4 (50.0)	4 (44.4)	2 (20.0)	6 (31.6)	10 (37.0)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	8	9	10	19	27
Mean (SD)	25.1 (9.30)	27.0 (7.91)	24.8 (5.83)	25.8 (6.78)	25.6 (7.43)
Median	22.5	24.0	24.5	24.0	24.0
Min, Max	11, 40	19, 43	17, 36	17, 43	11, 43
Age at the first onset of schizophrenia (years), n (%)					
n	8	9	10	19	27
19 or less	1 (12.5)	1 (11.1)	1 (10.0)	2 (10.5)	3 (11.1)
20 to 29	5 (62.5)	5 (55.6)	7 (70.0)	12 (63.2)	17 (63.0)
30 to 39	1 (12.5)	2 (22.2)	2 (20.0)	4 (21.1)	5 (18.5)
40 to 49	1 (12.5)	1 (11.1)	0	1 (5.3)	2 (7.4)
50 or more	0	0	0	0	0
Unknown	0	0	0	0	0

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Duration of illness (years)					
n	8	9	10	19	27
Mean (SD)	22.62 (17.273)	14.83 (13.837)	11.43 (11.481)	13.04 (12.411)	15.88 (14.382)
Median	28.21	8.45	6.46	8.18	8.45
Min, Max	1.1, 40.1	0.5, 42.3	1.6, 34.0	0.5, 42.3	0.5, 42.3
Duration of illness (years), n (%)					
n	8	9	10	19	27
<1	0	1 (11.1)	0	1 (5.3)	1 (3.7)
>=1 to <5	2 (25.0)	1 (11.1)	5 (50.0)	6 (31.6)	8 (29.6)
>=5 to <10	1 (12.5)	3 (33.3)	1 (10.0)	4 (21.1)	5 (18.5)
>=10 to <20	0	1 (11.1)	2 (20.0)	3 (15.8)	3 (11.1)
>=20 to <30	1 (12.5)	2 (22.2)	1 (10.0)	3 (15.8)	4 (14.8)
>=30	4 (50.0)	1 (11.1)	1 (10.0)	2 (10.5)	6 (22.2)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	8	9	10	19	27
Mean (SD)	2.93 (4.417)	12.39 (33.382)	6.58 (10.952)	9.33 (23.751)	7.44 (20.116)
Median	1.38	1.28	1.49	1.38	1.38
Min, Max	0.4, 13.7	0.4, 101.4	0.9, 33.3	0.4, 101.4	0.4, 101.4
Baseline PANSS total score					
n	8	9	10	19	27
Mean (SD)	96.0 (10.07)	97.0 (8.38)	94.8 (11.82)	95.8 (10.12)	95.9 (9.91)
Median	94.0	97.0	99.5	98.0	95.0
Min, Max	84, 117	85, 113	81, 116	81, 116	81, 117
PANSS composite subscale at baseline, n (%)					
n	8	9	10	19	27

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Positive subscale score>Negative subscale score	3 (37.5)	2 (22.2)	2 (20.0)	4 (21.1)	7 (25.9)
Positive subscale score=Negative subscale score	2 (25.0)	0	1 (10.0)	1 (5.3)	3 (11.1)
Positive subscale score<Negative subscale score	3 (37.5)	7 (77.8)	7 (70.0)	14 (73.7)	17 (63.0)
Baseline PANSS total score, n (%)					
n	8	9	10	19	27
<100	6 (75.0)	7 (77.8)	5 (50.0)	12 (63.2)	18 (66.7)
>=100 to <120	2 (25.0)	2 (22.2)	5 (50.0)	7 (36.8)	9 (33.3)
>=120	0	0	0	0	0
Baseline CGI-S score					
n	8	9	10	19	27
Mean (SD)	5.25 (0.707)	5.67 (0.707)	5.10 (0.568)	5.37 (0.684)	5.33 (0.679)
Median	5.00	6.00	5.00	5.00	5.00
Min, Max	4, 6	4, 6	4, 6	4, 6	4, 6
Baseline CGI-S score, n (%)					
n	8	9	10	19	27
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	1 (12.5)	1 (11.1)	1 (10.0)	2 (10.5)	3 (11.1)
5	4 (50.0)	1 (11.1)	7 (70.0)	8 (42.1)	12 (44.4)
6	3 (37.5)	7 (77.8)	2 (20.0)	9 (47.4)	12 (44.4)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	8	9	10	19	27
Mean (SD)	2.5 (4.78)	1.0 (1.50)	1.9 (2.81)	1.5 (2.27)	1.8 (3.15)

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Median	0.5	0.0	0.5	0.0	0.0
Min, Max	0, 14	0, 4	0, 7	0, 7	0, 14

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Number of episodes of schizophrenia					
n	3	7	7	14	17
Mean (SD)	5.0 (0.00)	3.7 (1.70)	3.7 (1.70)	3.7 (1.64)	3.9 (1.56)
Median	5.0	5.0	5.0	5.0	5.0
Min, Max	5, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	3	7	7	14	17
1	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
2	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
3	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
4	0	0	0	0	0
5 or more	3 (100.0)	4 (57.1)	4 (57.1)	8 (57.1)	11 (64.7)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	3	7	7	14	17
Mean (SD)	31.3 (6.35)	29.4 (12.18)	30.3 (8.24)	29.9 (10.00)	30.1 (9.31)
Median	35.0	27.0	28.0	28.0	28.0
Min, Max	24, 35	18, 53	21, 43	18, 53	18, 53
Age at the first onset of schizophrenia (years), n (%)					
n	3	7	7	14	17
19 or less	0	2 (28.6)	0	2 (14.3)	2 (11.8)
20 to 29	1 (33.3)	3 (42.9)	5 (71.4)	8 (57.1)	9 (52.9)
30 to 39	2 (66.7)	1 (14.3)	0	1 (7.1)	3 (17.6)
40 to 49	0	0	2 (28.6)	2 (14.3)	2 (11.8)
50 or more	0	1 (14.3)	0	1 (7.1)	1 (5.9)
Unknown	0	0	0	0	0

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Duration of illness (years)					
n	3	7	7	14	17
Mean (SD)	19.62 (7.396)	10.50 (5.780)	10.37 (9.413)	10.43 (7.505)	12.05 (8.102)
Median	17.80	10.80	8.40	10.10	10.95
Min, Max	13.3, 27.8	0.6, 17.5	0.5, 27.6	0.5, 27.6	0.5, 27.8
Duration of illness (years), n (%)					
n	3	7	7	14	17
<1	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
>=1 to <5	0	0	1 (14.3)	1 (7.1)	1 (5.9)
>=5 to <10	0	2 (28.6)	2 (28.6)	4 (28.6)	4 (23.5)
>=10 to <20	2 (66.7)	4 (57.1)	2 (28.6)	6 (42.9)	8 (47.1)
>=20 to <30	1 (33.3)	0	1 (14.3)	1 (7.1)	2 (11.8)
>=30	0	0	0	0	0
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	3	7	7	14	17
Mean (SD)	1.42 (0.294)	1.10 (0.363)	1.50 (0.675)	1.30 (0.560)	1.32 (0.518)
Median	1.58	1.05	1.77	1.36	1.38
Min, Max	1.1, 1.6	0.6, 1.6	0.3, 2.1	0.3, 2.1	0.3, 2.1
Baseline PANSS total score					
n	3	7	7	14	17
Mean (SD)	99.3 (17.39)	113.4 (17.58)	98.0 (14.55)	105.7 (17.45)	104.6 (17.07)
Median	93.0	119.0	96.0	107.0	99.0
Min, Max	86, 119	84, 133	82, 119	82, 133	82, 133
PANSS composite subscale at baseline, n (%)					
n	3	7	7	14	17

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Positive subscale score>Negative subscale score	1 (33.3)	5 (71.4)	4 (57.1)	9 (64.3)	10 (58.8)
Positive subscale score=Negative subscale score	0	0	0	0	0
Positive subscale score<Negative subscale score	2 (66.7)	2 (28.6)	3 (42.9)	5 (35.7)	7 (41.2)
Baseline PANSS total score, n (%)					
n	3	7	7	14	17
<100	2 (66.7)	2 (28.6)	5 (71.4)	7 (50.0)	9 (52.9)
>=100 to <120	1 (33.3)	2 (28.6)	2 (28.6)	4 (28.6)	5 (29.4)
>=120	0	3 (42.9)	0	3 (21.4)	3 (17.6)
Baseline CGI-S score					
n	3	7	7	14	17
Mean (SD)	4.67 (1.155)	5.43 (1.134)	4.43 (0.787)	4.93 (1.072)	4.88 (1.054)
Median	4.00	6.00	4.00	5.00	5.00
Min, Max	4, 6	3, 6	4, 6	3, 6	3, 6
Baseline CGI-S score, n (%)					
n	3	7	7	14	17
1	0	0	0	0	0
2	0	0	0	0	0
3	0	1 (14.3)	0	1 (7.1)	1 (5.9)
4	2 (66.7)	0	5 (71.4)	5 (35.7)	7 (41.2)
5	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
6	1 (33.3)	5 (71.4)	1 (14.3)	6 (42.9)	7 (41.2)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	3	7	7	14	17
Mean (SD)	5.3 (9.24)	0.0 (0.00)	1.1 (2.61)	0.6 (1.87)	1.4 (4.12)

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 16	0, 0	0, 7	0, 7	0, 16

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Number of episodes of schizophrenia					
n	43	55	54	109	152
Mean (SD)	3.4 (1.35)	3.5 (1.29)	3.5 (1.44)	3.5 (1.36)	3.5 (1.35)
Median	3.0	3.0	3.5	3.0	3.0
Min, Max	1, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	43	58	54	112	155
1	2 (4.7)	2 (3.4)	3 (5.6)	5 (4.5)	7 (4.5)
2	13 (30.2)	13 (22.4)	17 (31.5)	30 (26.8)	43 (27.7)
3	9 (20.9)	14 (24.1)	7 (13.0)	21 (18.8)	30 (19.4)
4	5 (11.6)	7 (12.1)	5 (9.3)	12 (10.7)	17 (11.0)
5 or more	14 (32.6)	19 (32.8)	22 (40.7)	41 (36.6)	55 (35.5)
Unknown	0	3 (5.2)	0	3 (2.7)	3 (1.9)
Age at the first onset of schizophrenia (years)					
n	41	56	52	108	149
Mean (SD)	28.1 (8.75)	25.3 (7.03)	25.7 (7.49)	25.5 (7.22)	26.2 (7.73)
Median	27.0	24.0	24.5	24.0	25.0
Min, Max	12, 49	15, 41	13, 55	13, 55	12, 55
Age at the first onset of schizophrenia (years), n (%)					
n	43	58	54	112	155
19 or less	7 (16.3)	11 (19.0)	9 (16.7)	20 (17.9)	27 (17.4)
20 to 29	17 (39.5)	30 (51.7)	30 (55.6)	60 (53.6)	77 (49.7)
30 to 39	14 (32.6)	13 (22.4)	11 (20.4)	24 (21.4)	38 (24.5)
40 to 49	3 (7.0)	2 (3.4)	1 (1.9)	3 (2.7)	6 (3.9)
50 or more	0	0	1 (1.9)	1 (0.9)	1 (0.6)
Unknown	2 (4.7)	2 (3.4)	2 (3.7)	4 (3.6)	6 (3.9)

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Duration of illness (years)					
n	41	56	52	108	149
Mean (SD)	12.17 (9.986)	11.39 (9.028)	9.33 (8.674)	10.40 (8.879)	10.89 (9.197)
Median	10.22	9.08	6.08	7.33	8.10
Min, Max	0.1, 40.6	0.0, 32.2	0.0, 38.6	0.0, 38.6	0.0, 40.6
Duration of illness (years), n (%)					
n	43	58	54	112	155
<1	6 (14.0)	5 (8.6)	5 (9.3)	10 (8.9)	16 (10.3)
>=1 to <5	5 (11.6)	13 (22.4)	16 (29.6)	29 (25.9)	34 (21.9)
>=5 to <10	8 (18.6)	10 (17.2)	12 (22.2)	22 (19.6)	30 (19.4)
>=10 to <20	15 (34.9)	18 (31.0)	12 (22.2)	30 (26.8)	45 (29.0)
>=20 to <30	4 (9.3)	8 (13.8)	6 (11.1)	14 (12.5)	18 (11.6)
>=30	3 (7.0)	2 (3.4)	1 (1.9)	3 (2.7)	6 (3.9)
Unknown	2 (4.7)	2 (3.4)	2 (3.7)	4 (3.6)	6 (3.9)
Duration of current episode (months)					
n	43	58	54	112	155
Mean (SD)	1.13 (0.605)	1.23 (1.719)	1.24 (0.615)	1.23 (1.303)	1.20 (1.152)
Median	1.08	0.95	1.13	1.03	1.05
Min, Max	0.2, 2.4	0.2, 13.3	0.2, 2.8	0.2, 13.3	0.2, 13.3
Baseline PANSS total score					
n	43	58	54	112	155
Mean (SD)	97.6 (13.71)	103.2 (15.90)	103.6 (17.35)	103.4 (16.54)	101.8 (15.98)
Median	93.0	101.0	100.0	101.0	100.0
Min, Max	80, 135	80, 147	82, 168	80, 168	80, 168
PANSS composite subscale at baseline, n (%)					
n	43	58	54	112	155

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Positive subscale score>Negative subscale score	26 (60.5)	38 (65.5)	23 (42.6)	61 (54.5)	87 (56.1)
Positive subscale score=Negative subscale score	2 (4.7)	3 (5.2)	2 (3.7)	5 (4.5)	7 (4.5)
Positive subscale score<Negative subscale score	15 (34.9)	17 (29.3)	29 (53.7)	46 (41.1)	61 (39.4)
Baseline PANSS total score, n (%)					
n	43	58	54	112	155
<100	25 (58.1)	25 (43.1)	27 (50.0)	52 (46.4)	77 (49.7)
>=100 to <120	16 (37.2)	23 (39.7)	18 (33.3)	41 (36.6)	57 (36.8)
>=120	2 (4.7)	10 (17.2)	9 (16.7)	19 (17.0)	21 (13.5)
Baseline CGI-S score					
n	43	58	54	112	155
Mean (SD)	4.86 (0.601)	4.91 (0.629)	5.15 (0.529)	5.03 (0.592)	4.98 (0.597)
Median	5.00	5.00	5.00	5.00	5.00
Min, Max	4, 6	4, 6	4, 6	4, 6	4, 6
Baseline CGI-S score, n (%)					
n	43	58	54	112	155
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	11 (25.6)	14 (24.1)	4 (7.4)	18 (16.1)	29 (18.7)
5	27 (62.8)	35 (60.3)	38 (70.4)	73 (65.2)	100 (64.5)
6	5 (11.6)	9 (15.5)	12 (22.2)	21 (18.8)	26 (16.8)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	43	58	54	112	155
Mean (SD)	0.2 (0.53)	0.3 (1.59)	0.1 (0.56)	0.2 (1.21)	0.2 (1.06)

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 3	0, 10	0, 3	0, 10	0, 10

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Number of episodes of schizophrenia					
n	22	22	22	44	66
Mean (SD)	3.5 (1.22)	3.7 (1.12)	4.0 (1.21)	3.8 (1.16)	3.7 (1.18)
Median	3.0	4.0	4.0	4.0	4.0
Min, Max	2, 5	2, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	22	22	22	44	66
1	0	0	1 (4.5)	1 (2.3)	1 (1.5)
2	6 (27.3)	4 (18.2)	2 (9.1)	6 (13.6)	12 (18.2)
3	6 (27.3)	5 (22.7)	4 (18.2)	9 (20.5)	15 (22.7)
4	3 (13.6)	6 (27.3)	5 (22.7)	11 (25.0)	14 (21.2)
5 or more	7 (31.8)	7 (31.8)	10 (45.5)	17 (38.6)	24 (36.4)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	22	22	22	44	66
Mean (SD)	23.7 (7.45)	23.6 (8.23)	22.4 (5.42)	23.0 (6.92)	23.2 (7.05)
Median	21.0	22.0	21.5	22.0	21.5
Min, Max	14, 41	11, 46	13, 35	11, 46	11, 46
Age at the first onset of schizophrenia (years), n (%)					
n	22	22	22	44	66
19 or less	6 (27.3)	8 (36.4)	7 (31.8)	15 (34.1)	21 (31.8)
20 to 29	12 (54.5)	8 (36.4)	12 (54.5)	20 (45.5)	32 (48.5)
30 to 39	3 (13.6)	5 (22.7)	3 (13.6)	8 (18.2)	11 (16.7)
40 to 49	1 (4.5)	1 (4.5)	0	1 (2.3)	2 (3.0)
50 or more	0	0	0	0	0
Unknown	0	0	0	0	0

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Duration of illness (years)					
n	22	22	22	44	66
Mean (SD)	9.99 (7.262)	8.90 (6.039)	10.05 (9.364)	9.48 (7.808)	9.65 (7.578)
Median	7.88	8.27	7.08	8.27	8.13
Min, Max	1.1, 23.1	2.4, 23.6	0.0, 32.4	0.0, 32.4	0.0, 32.4
Duration of illness (years), n (%)					
n	22	22	22	44	66
<1	0	0	2 (9.1)	2 (4.5)	2 (3.0)
>=1 to <5	7 (31.8)	7 (31.8)	7 (31.8)	14 (31.8)	21 (31.8)
>=5 to <10	6 (27.3)	7 (31.8)	5 (22.7)	12 (27.3)	18 (27.3)
>=10 to <20	6 (27.3)	6 (27.3)	4 (18.2)	10 (22.7)	16 (24.2)
>=20 to <30	3 (13.6)	2 (9.1)	3 (13.6)	5 (11.4)	8 (12.1)
>=30	0	0	1 (4.5)	1 (2.3)	1 (1.5)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	22	22	22	44	66
Mean (SD)	1.44 (0.585)	1.32 (0.689)	1.16 (0.637)	1.24 (0.661)	1.31 (0.639)
Median	1.36	1.23	1.10	1.15	1.22
Min, Max	0.4, 2.6	0.4, 3.0	0.4, 2.6	0.4, 3.0	0.4, 3.0
Baseline PANSS total score					
n	22	22	22	44	66
Mean (SD)	98.0 (12.04)	99.0 (15.40)	98.9 (13.12)	98.9 (14.14)	98.6 (13.39)
Median	96.0	93.5	95.0	94.0	94.0
Min, Max	81, 128	83, 138	80, 129	80, 138	80, 138
PANSS composite subscale at baseline, n (%)					
n	22	22	22	44	66

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Positive subscale score>Negative subscale score	9 (40.9)	16 (72.7)	11 (50.0)	27 (61.4)	36 (54.5)
Positive subscale score=Negative subscale score	1 (4.5)	0	2 (9.1)	2 (4.5)	3 (4.5)
Positive subscale score<Negative subscale score	12 (54.5)	6 (27.3)	9 (40.9)	15 (34.1)	27 (40.9)
Baseline PANSS total score, n (%)					
n	22	22	22	44	66
<100	12 (54.5)	15 (68.2)	14 (63.6)	29 (65.9)	41 (62.1)
>=100 to <120	8 (36.4)	4 (18.2)	6 (27.3)	10 (22.7)	18 (27.3)
>=120	2 (9.1)	3 (13.6)	2 (9.1)	5 (11.4)	7 (10.6)
Baseline CGI-S score					
n	22	22	22	44	66
Mean (SD)	4.82 (0.733)	4.82 (0.853)	4.86 (0.640)	4.84 (0.745)	4.83 (0.736)
Median	5.00	5.00	5.00	5.00	5.00
Min, Max	4, 6	4, 7	4, 6	4, 7	4, 7
Baseline CGI-S score, n (%)					
n	22	22	22	44	66
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	8 (36.4)	9 (40.9)	6 (27.3)	15 (34.1)	23 (34.8)
5	10 (45.5)	9 (40.9)	13 (59.1)	22 (50.0)	32 (48.5)
6	4 (18.2)	3 (13.6)	3 (13.6)	6 (13.6)	10 (15.2)
7	0	1 (4.5)	0	1 (2.3)	1 (1.5)
Baseline DIEPSS total score (excluding overall severity)					
n	22	22	22	44	66
Mean (SD)	0.2 (0.61)	0.0 (0.00)	0.2 (0.75)	0.1 (0.54)	0.2 (0.56)

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 2	0, 0	0, 3	0, 3	0, 3

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Number of episodes of schizophrenia					
n	10	13	12	25	35
Mean (SD)	4.5 (1.08)	4.5 (0.78)	4.7 (0.65)	4.6 (0.71)	4.6 (0.81)
Median	5.0	5.0	5.0	5.0	5.0
Min, Max	2, 5	3, 5	3, 5	3, 5	2, 5
Number of episodes of schizophrenia, n (%)					
n	10	13	12	25	35
1	0	0	0	0	0
2	1 (10.0)	0	0	0	1 (2.9)
3	1 (10.0)	2 (15.4)	1 (8.3)	3 (12.0)	4 (11.4)
4	0	2 (15.4)	2 (16.7)	4 (16.0)	4 (11.4)
5 or more	8 (80.0)	9 (69.2)	9 (75.0)	18 (72.0)	26 (74.3)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	10	13	12	25	35
Mean (SD)	23.0 (8.49)	23.2 (7.26)	27.8 (11.55)	25.4 (9.64)	24.7 (9.27)
Median	23.0	23.0	23.5	23.0	23.0
Min, Max	6, 40	8, 32	14, 50	8, 50	6, 50
Age at the first onset of schizophrenia (years), n (%)					
n	10	13	12	25	35
19 or less	2 (20.0)	3 (23.1)	2 (16.7)	5 (20.0)	7 (20.0)
20 to 29	7 (70.0)	7 (53.8)	6 (50.0)	13 (52.0)	20 (57.1)
30 to 39	0	3 (23.1)	2 (16.7)	5 (20.0)	5 (14.3)
40 to 49	1 (10.0)	0	1 (8.3)	1 (4.0)	2 (5.7)
50 or more	0	0	1 (8.3)	1 (4.0)	1 (2.9)
Unknown	0	0	0	0	0

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Duration of illness (years)					
n	10	13	12	25	35
Mean (SD)	10.61 (8.062)	16.32 (11.293)	14.82 (8.853)	15.60 (10.013)	14.17 (9.655)
Median	10.03	15.13	14.12	15.13	13.11
Min, Max	0.9, 29.1	2.4, 38.1	3.2, 28.1	2.4, 38.1	0.9, 38.1
Duration of illness (years), n (%)					
n	10	13	12	25	35
<1	2 (20.0)	0	0	0	2 (5.7)
>=1 to <5	0	3 (23.1)	1 (8.3)	4 (16.0)	4 (11.4)
>=5 to <10	3 (30.0)	1 (7.7)	4 (33.3)	5 (20.0)	8 (22.9)
>=10 to <20	4 (40.0)	4 (30.8)	3 (25.0)	7 (28.0)	11 (31.4)
>=20 to <30	1 (10.0)	3 (23.1)	4 (33.3)	7 (28.0)	8 (22.9)
>=30	0	2 (15.4)	0	2 (8.0)	2 (5.7)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	10	13	12	25	35
Mean (SD)	1.10 (0.517)	1.19 (0.627)	1.53 (0.609)	1.35 (0.629)	1.28 (0.603)
Median	1.25	1.25	1.51	1.48	1.28
Min, Max	0.2, 1.8	0.3, 2.2	0.3, 2.5	0.3, 2.5	0.2, 2.5
Baseline PANSS total score					
n	10	13	12	25	35
Mean (SD)	100.7 (10.30)	104.7 (20.89)	102.0 (12.63)	103.4 (17.12)	102.6 (15.38)
Median	97.5	99.0	104.0	101.0	99.0
Min, Max	86, 119	87, 146	85, 129	85, 146	85, 146
PANSS composite subscale at baseline, n (%)					
n	10	13	12	25	35

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Positive subscale score>Negative subscale score	6 (60.0)	6 (46.2)	6 (50.0)	12 (48.0)	18 (51.4)
Positive subscale score=Negative subscale score	1 (10.0)	1 (7.7)	1 (8.3)	2 (8.0)	3 (8.6)
Positive subscale score<Negative subscale score	3 (30.0)	6 (46.2)	5 (41.7)	11 (44.0)	14 (40.0)
Baseline PANSS total score, n (%)					
n	10	13	12	25	35
<100	6 (60.0)	8 (61.5)	4 (33.3)	12 (48.0)	18 (51.4)
>=100 to <120	4 (40.0)	2 (15.4)	7 (58.3)	9 (36.0)	13 (37.1)
>=120	0	3 (23.1)	1 (8.3)	4 (16.0)	4 (11.4)
Baseline CGI-S score					
n	10	13	12	25	35
Mean (SD)	4.60 (0.516)	4.92 (0.760)	4.67 (0.778)	4.80 (0.764)	4.74 (0.701)
Median	5.00	5.00	4.50	5.00	5.00
Min, Max	4, 5	4, 6	4, 6	4, 6	4, 6
Baseline CGI-S score, n (%)					
n	10	13	12	25	35
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	4 (40.0)	4 (30.8)	6 (50.0)	10 (40.0)	14 (40.0)
5	6 (60.0)	6 (46.2)	4 (33.3)	10 (40.0)	16 (45.7)
6	0	3 (23.1)	2 (16.7)	5 (20.0)	5 (14.3)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	10	13	12	25	35
Mean (SD)	1.1 (2.28)	1.9 (3.95)	1.3 (2.19)	1.6 (3.17)	1.5 (2.92)

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 7	0, 12	0, 7	0, 12	0, 12

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Number of episodes of schizophrenia					
n	5	15	16	31	36
Mean (SD)	2.8 (1.30)	3.1 (1.22)	3.4 (1.36)	3.2 (1.28)	3.2 (1.28)
Median	2.0	3.0	3.5	3.0	3.0
Min, Max	2, 5	2, 5	2, 5	2, 5	2, 5
Number of episodes of schizophrenia, n (%)					
n	5	15	17	32	37
1	0	0	0	0	0
2	3 (60.0)	7 (46.7)	7 (41.2)	14 (43.8)	17 (45.9)
3	1 (20.0)	3 (20.0)	1 (5.9)	4 (12.5)	5 (13.5)
4	0	2 (13.3)	3 (17.6)	5 (15.6)	5 (13.5)
5 or more	1 (20.0)	3 (20.0)	5 (29.4)	8 (25.0)	9 (24.3)
Unknown	0	0	1 (5.9)	1 (3.1)	1 (2.7)
Age at the first onset of schizophrenia (years)					
n	5	15	17	32	37
Mean (SD)	30.6 (7.27)	27.9 (4.82)	29.1 (11.23)	28.5 (8.71)	28.8 (8.47)
Median	32.0	28.0	26.0	27.0	28.0
Min, Max	18, 36	20, 37	17, 60	17, 60	17, 60
Age at the first onset of schizophrenia (years), n (%)					
n	5	15	17	32	37
19 or less	1 (20.0)	0	2 (11.8)	2 (6.3)	3 (8.1)
20 to 29	0	10 (66.7)	10 (58.8)	20 (62.5)	20 (54.1)
30 to 39	4 (80.0)	5 (33.3)	3 (17.6)	8 (25.0)	12 (32.4)
40 to 49	0	0	0	0	0
50 or more	0	0	2 (11.8)	2 (6.3)	2 (5.4)
Unknown	0	0	0	0	0

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Duration of illness (years)					
n	5	15	17	32	37
Mean (SD)	11.37 (10.101)	10.96 (7.899)	14.29 (10.022)	12.73 (9.103)	12.55 (9.106)
Median	10.01	8.00	13.11	10.23	10.09
Min, Max	0.5, 26.4	1.6, 26.6	0.3, 36.3	0.3, 36.3	0.3, 36.3
Duration of illness (years), n (%)					
n	5	15	17	32	37
<1	1 (20.0)	0	2 (11.8)	2 (6.3)	3 (8.1)
>=1 to <5	1 (20.0)	4 (26.7)	2 (11.8)	6 (18.8)	7 (18.9)
>=5 to <10	0	5 (33.3)	2 (11.8)	7 (21.9)	7 (18.9)
>=10 to <20	2 (40.0)	3 (20.0)	7 (41.2)	10 (31.3)	12 (32.4)
>=20 to <30	1 (20.0)	3 (20.0)	3 (17.6)	6 (18.8)	7 (18.9)
>=30	0	0	1 (5.9)	1 (3.1)	1 (2.7)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	5	15	17	32	37
Mean (SD)	0.83 (0.732)	0.99 (0.407)	0.83 (0.437)	0.90 (0.424)	0.90 (0.464)
Median	0.53	1.02	0.62	0.85	0.79
Min, Max	0.1, 2.0	0.1, 1.6	0.2, 1.8	0.1, 1.8	0.1, 2.0
Baseline PANSS total score					
n	5	15	17	32	37
Mean (SD)	109.8 (20.20)	91.6 (8.42)	93.4 (9.13)	92.6 (8.71)	94.9 (12.10)
Median	108.0	91.0	93.0	92.5	94.0
Min, Max	86, 138	81, 109	80, 113	80, 113	80, 138
PANSS composite subscale at baseline, n (%)					
n	5	15	17	32	37

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Positive subscale score>Negative subscale score	3 (60.0)	7 (46.7)	12 (70.6)	19 (59.4)	22 (59.5)
Positive subscale score=Negative subscale score	0	2 (13.3)	0	2 (6.3)	2 (5.4)
Positive subscale score<Negative subscale score	2 (40.0)	6 (40.0)	5 (29.4)	11 (34.4)	13 (35.1)
Baseline PANSS total score, n (%)					
n	5	15	17	32	37
<100	2 (40.0)	12 (80.0)	14 (82.4)	26 (81.3)	28 (75.7)
>=100 to <120	1 (20.0)	3 (20.0)	3 (17.6)	6 (18.8)	7 (18.9)
>=120	2 (40.0)	0	0	0	2 (5.4)
Baseline CGI-S score					
n	5	15	17	32	37
Mean (SD)	5.60 (1.140)	4.67 (0.724)	5.12 (0.928)	4.91 (0.856)	5.00 (0.913)
Median	6.00	5.00	5.00	5.00	5.00
Min, Max	4, 7	4, 6	4, 7	4, 7	4, 7
Baseline CGI-S score, n (%)					
n	5	15	17	32	37
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	1 (20.0)	7 (46.7)	5 (29.4)	12 (37.5)	13 (35.1)
5	1 (20.0)	6 (40.0)	6 (35.3)	12 (37.5)	13 (35.1)
6	2 (40.0)	2 (13.3)	5 (29.4)	7 (21.9)	9 (24.3)
7	1 (20.0)	0	1 (5.9)	1 (3.1)	2 (5.4)
Baseline DIEPSS total score (excluding overall severity)					
n	5	15	17	32	37
Mean (SD)	2.2 (4.38)	0.6 (1.12)	1.5 (2.70)	1.1 (2.12)	1.2 (2.48)

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 10	0, 4	0, 8	0, 8	0, 10

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Number of episodes of schizophrenia					
n	13	17	15	32	45
Mean (SD)	4.8 (0.60)	4.9 (0.33)	4.9 (0.26)	4.9 (0.30)	4.9 (0.40)
Median	5.0	5.0	5.0	5.0	5.0
Min, Max	3, 5	4, 5	4, 5	4, 5	3, 5
Number of episodes of schizophrenia, n (%)					
n	13	17	15	32	45
1	0	0	0	0	0
2	0	0	0	0	0
3	1 (7.7)	0	0	0	1 (2.2)
4	1 (7.7)	2 (11.8)	1 (6.7)	3 (9.4)	4 (8.9)
5 or more	11 (84.6)	15 (88.2)	14 (93.3)	29 (90.6)	40 (88.9)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	13	17	15	32	45
Mean (SD)	24.5 (6.21)	28.2 (7.70)	24.4 (9.07)	26.4 (8.45)	25.8 (7.85)
Median	22.0	26.0	25.0	25.5	25.0
Min, Max	16, 39	18, 49	8, 47	8, 49	8, 49
Age at the first onset of schizophrenia (years), n (%)					
n	13	17	15	32	45
19 or less	2 (15.4)	1 (5.9)	3 (20.0)	4 (12.5)	6 (13.3)
20 to 29	8 (61.5)	9 (52.9)	9 (60.0)	18 (56.3)	26 (57.8)
30 to 39	3 (23.1)	5 (29.4)	2 (13.3)	7 (21.9)	10 (22.2)
40 to 49	0	2 (11.8)	1 (6.7)	3 (9.4)	3 (6.7)
50 or more	0	0	0	0	0
Unknown	0	0	0	0	0

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Duration of illness (years)					
n	13	17	15	32	45
Mean (SD)	14.84 (7.360)	16.38 (9.050)	14.75 (11.610)	15.61 (10.190)	15.39 (9.384)
Median	14.52	16.11	14.11	14.61	14.52
Min, Max	5.0, 27.1	1.8, 33.1	3.1, 44.1	1.8, 44.1	1.8, 44.1
Duration of illness (years), n (%)					
n	13	17	15	32	45
<1	0	0	0	0	0
>=1 to <5	1 (7.7)	1 (5.9)	4 (26.7)	5 (15.6)	6 (13.3)
>=5 to <10	3 (23.1)	5 (29.4)	3 (20.0)	8 (25.0)	11 (24.4)
>=10 to <20	5 (38.5)	6 (35.3)	4 (26.7)	10 (31.3)	15 (33.3)
>=20 to <30	4 (30.8)	4 (23.5)	2 (13.3)	6 (18.8)	10 (22.2)
>=30	0	1 (5.9)	2 (13.3)	3 (9.4)	3 (6.7)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	13	17	15	32	45
Mean (SD)	1.34 (0.652)	0.95 (0.651)	0.96 (0.595)	0.96 (0.615)	1.07 (0.644)
Median	1.28	0.62	1.08	0.90	1.08
Min, Max	0.3, 2.5	0.2, 2.2	0.2, 2.2	0.2, 2.2	0.2, 2.5
Baseline PANSS total score					
n	13	17	15	32	45
Mean (SD)	100.8 (8.42)	100.4 (6.17)	101.2 (6.25)	100.8 (6.12)	100.8 (6.76)
Median	104.0	99.0	102.0	100.5	101.0
Min, Max	83, 115	91, 114	88, 114	88, 114	83, 115
PANSS composite subscale at baseline, n (%)					
n	13	17	15	32	45

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Positive subscale score>Negative subscale score	7 (53.8)	7 (41.2)	6 (40.0)	13 (40.6)	20 (44.4)
Positive subscale score=Negative subscale score	1 (7.7)	3 (17.6)	0	3 (9.4)	4 (8.9)
Positive subscale score<Negative subscale score	5 (38.5)	7 (41.2)	9 (60.0)	16 (50.0)	21 (46.7)
Baseline PANSS total score, n (%)					
n	13	17	15	32	45
<100	6 (46.2)	9 (52.9)	5 (33.3)	14 (43.8)	20 (44.4)
>=100 to <120	7 (53.8)	8 (47.1)	10 (66.7)	18 (56.3)	25 (55.6)
>=120	0	0	0	0	0
Baseline CGI-S score					
n	13	17	15	32	45
Mean (SD)	4.54 (0.519)	4.65 (0.606)	4.87 (0.352)	4.75 (0.508)	4.69 (0.514)
Median	5.00	5.00	5.00	5.00	5.00
Min, Max	4, 5	4, 6	4, 5	4, 6	4, 6
Baseline CGI-S score, n (%)					
n	13	17	15	32	45
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	6 (46.2)	7 (41.2)	2 (13.3)	9 (28.1)	15 (33.3)
5	7 (53.8)	9 (52.9)	13 (86.7)	22 (68.8)	29 (64.4)
6	0	1 (5.9)	0	1 (3.1)	1 (2.2)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	13	17	15	32	45
Mean (SD)	1.1 (2.06)	0.6 (1.80)	0.5 (0.99)	0.6 (1.46)	0.7 (1.64)
Median	0.0	0.0	0.0	0.0	0.0

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Min, Max	0, 7	0, 7	0, 3	0, 7	0, 7

The denominator of percentages is the number of subjects in analysis population of subgroup. Duration of illness is years from the initial episode of schizophrenia to the informed consent. Duration of current episode is months from the onset of current episode to the informed consent. In regard to 'Number of episodes of schizophrenia', a category '5 or more' is set to 5 for descriptive purpose. The data cut-off at Open-Week 24 was used.

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表2.7.4.7-15　ロナセンテープ貼付期間（20試験・ロナセンテープ貼付期、Open-52週）
DSP-5423P Dosed Population

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 196)	80MG-to-FLEX DOSE (N = 194)	Active-to-FLEX DOSE (N = 390)	Overall-to-FLEX DOSE (N = 521)
Duration of exposure (days)					
n	131	196	194	390	521
Mean (SD)	169.2 (93.32)	158.7 (121.30)	186.3 (119.04)	172.4 (120.82)	171.6 (114.45)
Median	195.0	170.0	233.0	230.0	196.0
Min, Max	2, 377	1, 418	1, 414	1, 418	1, 418
Duration of exposure (weeks), n (%)					
1 to 6	16 (12.2)	53 (27.0)	37 (19.1)	90 (23.1)	106 (20.3)
7 to 12	13 (9.9)	25 (12.8)	19 (9.8)	44 (11.3)	57 (10.9)
13 to 24	15 (11.5)	20 (10.2)	20 (10.3)	40 (10.3)	55 (10.6)
25 to 36	72 (55.0)	78 (39.8)	90 (46.4)	168 (43.1)	240 (46.1)
37 to 48	1 (0.8)	3 (1.5)	5 (2.6)	8 (2.1)	9 (1.7)
49 or more	14 (10.7)	17 (8.7)	23 (11.9)	40 (10.3)	54 (10.4)
Mean daily dose (mg/day)					
n	131	196	194	390	521
Mean (SD)	62.1 (14.45)	51.9 (13.13)	69.8 (11.47)	60.8 (15.23)	61.1 (15.04)
Median	66.4	46.7	75.2	63.1	64.1
Min, Max	40, 79	39, 75	44, 80	39, 80	39, 80
Maximum daily dose, n (%)					
n	131	196	194	390	521
40 mg	23 (17.6)	87 (44.4)	0	87 (22.3)	110 (21.1)
60 mg	27 (20.6)	31 (15.8)	0	31 (7.9)	58 (11.1)
80 mg	81 (61.8)	78 (39.8)	194 (100.0)	272 (69.7)	353 (67.8)
Modal daily dose, n (%)					

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 196)	80MG-to-FLEX DOSE (N = 194)	Active-to-FLEX DOSE (N = 390)	Overall-to-FLEX DOSE (N = 521)
n	131	196	194	390	521
40 mg	38 (29.0)	117 (59.7)	36 (18.6)	153 (39.2)	191 (36.7)
60 mg	28 (21.4)	22 (11.2)	21 (10.8)	43 (11.0)	71 (13.6)
80 mg	65 (49.6)	57 (29.1)	137 (70.6)	194 (49.7)	259 (49.7)
Last daily dose (mg/day)					
n	131	196	194	390	521
Mean (SD)	66.7 (16.57)	58.5 (18.33)	68.7 (16.01)	63.5 (17.93)	64.3 (17.64)
Median	80.0	60.0	80.0	80.0	80.0
Min, Max	40, 80	40, 80	40, 80	40, 80	40, 80
Last daily dose, n (%)					
40 mg	30 (22.9)	90 (45.9)	38 (19.6)	128 (32.8)	158 (30.3)
60 mg	27 (20.6)	31 (15.8)	34 (17.5)	65 (16.7)	92 (17.7)
80 mg	74 (56.5)	75 (38.3)	122 (62.9)	197 (50.5)	271 (52.0)
Cumulative dose (mg)					
n	131	196	194	390	521
Mean (SD)	10606.7 (6457.73)	9285.3 (8331.79)	12440.6 (8084.71)	10854.9 (8350.04)	10792.5 (7911.73)
Median	10640.0	9280.0	11890.0	10550.0	10640.0
Min, Max	80, 29260	40, 31340	80, 32620	40, 32620	40, 32620

Duration of exposure = last dose date – first dose date + 1, during the DSP-5423P treatment period. Duration will not be calculated if either date is missing. Modal daily dose is the most frequently prescribed daily dose during the DSP-5423P treatment period. In the case that two or more dose are the most frequent dose, the maximum of them will be the modal daily dose. Note that for the DSP-5423P treatment period, and subjects who take placebo in the double-blind treatment phase, initial application date will be a one that DSP-5423P is initially applied. The final data at Open-Week 52 was used.

Control No:<<t14-01-10-04-ex.sas, 2018-11-14T20:05:04>>

表2.7.4.7-16　人口統計学的特性及びその他の特性（20試験・ロナセンテープ貼付期、Open-52週）
DSP-5423P Dosed Population

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 196)	80MG-to-FLEX DOSE (N = 194)	Active-to-FLEX DOSE (N = 390)	Overall-to-FLEX DOSE (N = 521)
Sex, n (%)					
n	131	196	194	390	521
Male	85 (64.9)	116 (59.2)	115 (59.3)	231 (59.2)	316 (60.7)
Female	46 (35.1)	80 (40.8)	79 (40.7)	159 (40.8)	205 (39.3)
Age (years)					
n	131	196	194	390	521
Mean (SD)	41.7 (13.10)	40.7 (13.34)	40.6 (14.31)	40.6 (13.81)	40.9 (13.63)
Median	41.0	40.0	38.0	39.0	39.0
Min, Max	18, 73	18, 79	18, 81	18, 81	18, 81
Age (years), n (%)					
n	131	196	194	390	521
<65	123 (93.9)	185 (94.4)	182 (93.8)	367 (94.1)	490 (94.0)
>=65	8 (6.1)	11 (5.6)	12 (6.2)	23 (5.9)	31 (6.0)
Race, n (%)					
n	131	196	194	390	521
Asian	108 (82.4)	167 (85.2)	167 (86.1)	334 (85.6)	442 (84.8)
White	23 (17.6)	29 (14.8)	27 (13.9)	56 (14.4)	79 (15.2)
Ethnicity, n (%)					
n	131	196	194	390	521
Not Hispanic or Latino	131 (100.0)	196 (100.0)	194 (100.0)	390 (100.0)	521 (100.0)
Country, n (%)					
n	131	196	194	390	521

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 196)	80MG-to-FLEX DOSE (N = 194)	Active-to-FLEX DOSE (N = 390)	Overall-to-FLEX DOSE (N = 521)
Japan	27 (20.6)	55 (28.1)	57 (29.4)	112 (28.7)	139 (26.7)
China	8 (6.1)	9 (4.6)	10 (5.2)	19 (4.9)	27 (5.2)
Korea	3 (2.3)	7 (3.6)	7 (3.6)	14 (3.6)	17 (3.3)
Malaysia	43 (32.8)	58 (29.6)	54 (27.8)	112 (28.7)	155 (29.8)
Philippines	22 (16.8)	22 (11.2)	22 (11.3)	44 (11.3)	66 (12.7)
Russia	10 (7.6)	13 (6.6)	12 (6.2)	25 (6.4)	35 (6.7)
Taiwan	5 (3.8)	15 (7.7)	17 (8.8)	32 (8.2)	37 (7.1)
Ukraine	13 (9.9)	17 (8.7)	15 (7.7)	32 (8.2)	45 (8.6)
Height (cm)					
n	131	196	194	390	521
Mean (SD)	164.35 (10.312)	163.55 (9.455)	163.43 (9.555)	163.49 (9.492)	163.70 (9.702)
Median	164.00	164.00	164.15	164.00	164.00
Min, Max	137.0, 200.0	125.0, 185.0	130.5, 183.0	125.0, 185.0	125.0, 200.0
Weight (kg)					
n	131	196	194	390	521
Mean (SD)	66.06 (17.065)	63.09 (14.656)	62.69 (14.547)	62.89 (14.585)	63.69 (15.291)
Median	62.70	59.85	60.65	60.00	60.80
Min, Max	39.6, 149.8	35.8, 118.0	27.9, 118.7	27.9, 118.7	27.9, 149.8
BMI (kg/m^2)					
n	131	196	194	390	521
Mean (SD)	24.36 (5.248)	23.56 (5.036)	23.39 (4.792)	23.48 (4.911)	23.70 (5.007)
Median	23.18	22.60	22.51	22.54	22.77
Min, Max	16.9, 44.2	14.5, 46.8	13.6, 45.8	13.6, 46.8	13.6, 46.8
Any concomitant diseases, n (%)					
n	131	196	194	390	521
Yes	66 (50.4)	112 (57.1)	112 (57.7)	224 (57.4)	290 (55.7)

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 196)	80MG-to-FLEX DOSE (N = 194)	Active-to-FLEX DOSE (N = 390)	Overall-to-FLEX DOSE (N = 521)
No	65 (49.6)	84 (42.9)	82 (42.3)	166 (42.6)	231 (44.3)
Hospitalization status at informed consent, n (%)					
n	131	196	194	390	521
Inpatient	127 (96.9)	188 (95.9)	189 (97.4)	377 (96.7)	504 (96.7)
Within 3 months (90 days)	118 (90.1)	168 (85.7)	174 (89.7)	342 (87.7)	460 (88.3)
Over 3 months	8 (6.1)	20 (10.2)	15 (7.7)	35 (9.0)	43 (8.3)
Unknown	1 (0.8)	0	0	0	1 (0.2)
Outpatient	4 (3.1)	8 (4.1)	5 (2.6)	13 (3.3)	17 (3.3)

The denominator of percentages is the number of subjects in analysis population. The final data at Open-Week 52 was used.
Control No:<<t14-01-04-06-dm.sas, 2018-11-14T20:03:36>>

表2.7.4.7-17　疾患データ（20試験・ロナセンテープ貼付期、Open-52週）
DSP-5423P Dosed Population

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 196)	80MG-to-FLEX DOSE (N = 194)	Active-to-FLEX DOSE (N = 390)	Overall-to-FLEX DOSE (N = 521)
Number of episodes of schizophrenia					
n	128	178	184	362	490
Mean (SD)	3.7 (1.36)	3.7 (1.33)	3.8 (1.37)	3.7 (1.35)	3.7 (1.35)
Median	4.0	4.0	4.0	4.0	4.0
Min, Max	1, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	131	196	194	390	521
1	6 (4.6)	8 (4.1)	10 (5.2)	18 (4.6)	24 (4.6)
2	27 (20.6)	38 (19.4)	37 (19.1)	75 (19.2)	102 (19.6)
3	23 (17.6)	35 (17.9)	24 (12.4)	59 (15.1)	82 (15.7)
4	12 (9.2)	23 (11.7)	22 (11.3)	45 (11.5)	57 (10.9)
5 or more	60 (45.8)	74 (37.8)	91 (46.9)	165 (42.3)	225 (43.2)
Unknown	3 (2.3)	18 (9.2)	10 (5.2)	28 (7.2)	31 (6.0)
Age at the first onset of schizophrenia (years)					
n	129	192	191	383	512
Mean (SD)	26.9 (9.02)	26.8 (9.49)	26.5 (9.60)	26.7 (9.53)	26.7 (9.40)
Median	26.0	24.0	24.0	24.0	25.0
Min, Max	6, 58	8, 67	8, 60	8, 67	6, 67
Age at the first onset of schizophrenia (years), n (%)					
n	131	196	194	390	521
19 or less	25 (19.1)	38 (19.4)	40 (20.6)	78 (20.0)	103 (19.8)
20 to 29	58 (44.3)	94 (48.0)	97 (50.0)	191 (49.0)	249 (47.8)
30 to 39	35 (26.7)	41 (20.9)	34 (17.5)	75 (19.2)	110 (21.1)
40 to 49	10 (7.6)	13 (6.6)	13 (6.7)	26 (6.7)	36 (6.9)

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 196)	80MG-to-FLEX DOSE (N = 194)	Active-to-FLEX DOSE (N = 390)	Overall-to-FLEX DOSE (N = 521)
50 or more	1 (0.8)	6 (3.1)	7 (3.6)	13 (3.3)	14 (2.7)
Unknown	2 (1.5)	4 (2.0)	3 (1.5)	7 (1.8)	9 (1.7)
Duration of illness (years)					
n	129	192	191	383	512
Mean (SD)	14.76 (12.287)	13.79 (11.196)	13.78 (12.197)	13.78 (11.691)	14.03 (11.839)
Median	11.35	11.05	9.71	10.66	10.80
Min, Max	0.1, 47.8	0.0, 55.2	0.0, 50.6	0.0, 55.2	0.0, 55.2
Duration of illness (years), n (%)					
n	131	196	194	390	521
<1	11 (8.4)	11 (5.6)	11 (5.7)	22 (5.6)	33 (6.3)
>=1 to <5	20 (15.3)	38 (19.4)	44 (22.7)	82 (21.0)	102 (19.6)
>=5 to <10	25 (19.1)	38 (19.4)	42 (21.6)	80 (20.5)	105 (20.2)
>=10 to <20	37 (28.2)	57 (29.1)	45 (23.2)	102 (26.2)	139 (26.7)
>=20 to <30	20 (15.3)	31 (15.8)	30 (15.5)	61 (15.6)	81 (15.5)
>=30	16 (12.2)	17 (8.7)	19 (9.8)	36 (9.2)	52 (10.0)
Unknown	2 (1.5)	4 (2.0)	3 (1.5)	7 (1.8)	9 (1.7)
Duration of current episode (months)					
n	131	196	194	390	521
Mean (SD)	3.69 (26.544)	3.71 (25.866)	3.84 (32.103)	3.77 (29.098)	3.75 (28.453)
Median	1.22	1.10	1.17	1.13	1.15
Min, Max	0.1, 304.8	0.0, 348.9	0.2, 447.0	0.0, 447.0	0.0, 447.0
Baseline PANSS total score					
n	131	196	194	390	521
Mean (SD)	99.6 (13.67)	101.6 (15.55)	101.5 (14.69)	101.6 (15.11)	101.1 (14.77)
Median	96.0	99.0	99.0	99.0	99.0
Min, Max	80, 141	80, 157	80, 168	80, 168	80, 168

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 196)	80MG-to-FLEX DOSE (N = 194)	Active-to-FLEX DOSE (N = 390)	Overall-to-FLEX DOSE (N = 521)
PANSS composite subscale at baseline, n (%)					
n	131	196	194	390	521
Positive subscale score>Negative subscale score	64 (48.9)	104 (53.1)	85 (43.8)	189 (48.5)	253 (48.6)
Positive subscale score=Negative subscale score	8 (6.1)	11 (5.6)	11 (5.7)	22 (5.6)	30 (5.8)
Positive subscale score<Negative subscale score	59 (45.0)	81 (41.3)	98 (50.5)	179 (45.9)	238 (45.7)
Baseline PANSS total score, n (%)					
n	131	196	194	390	521
<100	73 (55.7)	105 (53.6)	99 (51.0)	204 (52.3)	277 (53.2)
>=100 to <120	48 (36.6)	63 (32.1)	75 (38.7)	138 (35.4)	186 (35.7)
>=120	10 (7.6)	28 (14.3)	20 (10.3)	48 (12.3)	58 (11.1)
Baseline CGI-S score					
n	131	196	194	390	521
Mean (SD)	4.79 (0.713)	4.84 (0.780)	4.92 (0.734)	4.88 (0.758)	4.86 (0.747)
Median	5.00	5.00	5.00	5.00	5.00
Min, Max	4, 7	3, 7	3, 7	3, 7	3, 7
Baseline CGI-S score, n (%)					
n	131	196	194	390	521
1	0	0	0	0	0
2	0	0	0	0	0
3	0	2 (1.0)	1 (0.5)	3 (0.8)	3 (0.6)
4	49 (37.4)	70 (35.7)	54 (27.8)	124 (31.8)	173 (33.2)
5	62 (47.3)	84 (42.9)	101 (52.1)	185 (47.4)	247 (47.4)
6	19 (14.5)	38 (19.4)	35 (18.0)	73 (18.7)	92 (17.7)
7	1 (0.8)	2 (1.0)	3 (1.5)	5 (1.3)	6 (1.2)
Baseline DIEPSS total score (excluding overall severity)					

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 196)	80MG-to-FLEX DOSE (N = 194)	Active-to-FLEX DOSE (N = 390)	Overall-to-FLEX DOSE (N = 521)
n	131	196	193	389	520
Mean (SD)	1.0 (2.60)	0.8 (2.25)	1.0 (2.42)	0.9 (2.34)	0.9 (2.40)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 16	0, 14	0, 14	0, 14	0, 16

The denominator of percentages is the number of subjects in analysis population. Duration of illness is years from the initial episode of schizophrenia to the informed consent. Duration of current episode is months from the onset of current episode to the informed consent. In regard to 'Number of episodes of schizophrenia', a category '5 or more' is set to 5 for descriptive purpose. The final data at Open-Week 52 was used.

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表2.7.4.7-18　主な有害事象の副作用発現割合（20試験・ロナセンテープ貼付期、Open-52週）
20試験 DSP-5423P Dosed Population

System Organ Class Preferred Term	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Subjects with any treatment-related TEAE	73 (55.7)	113 (57.7)	124 (63.9)	237 (60.8)	310 (59.5)
内分泌障害	3 (2.3)	5 (2.6)	4 (2.1)	9 (2.3)	12 (2.3)
高プロラクチン血症	3 (2.3)	5 (2.6)	4 (2.1)	9 (2.3)	12 (2.3)
胃腸障害	9 (6.9)	14 (7.1)	28 (14.4)	42 (10.8)	51 (9.8)
流涎過多	3 (2.3)	5 (2.6)	10 (5.2)	15 (3.8)	18 (3.5)
便秘	3 (2.3)	4 (2.0)	9 (4.6)	13 (3.3)	16 (3.1)
嘔吐	0	1 (0.5)	3 (1.5)	4 (1.0)	4 (0.8)
下痢	0	0	3 (1.5)	3 (0.8)	3 (0.6)
歯痛	0	1 (0.5)	0	1 (0.3)	1 (0.2)
一般・全身障害および投与部位の状態	20 (15.3)	38 (19.4)	59 (30.4)	97 (24.9)	117 (22.5)
適用部位紅斑	8 (6.1)	10 (5.1)	22 (11.3)	32 (8.2)	40 (7.7)
適用部位そう痒感	4 (3.1)	14 (7.1)	19 (9.8)	33 (8.5)	37 (7.1)
適用部位皮膚炎	2 (1.5)	4 (2.0)	6 (3.1)	10 (2.6)	12 (2.3)
感染症および寄生虫症	1 (0.8)	4 (2.0)	2 (1.0)	6 (1.5)	7 (1.3)
上気道感染	0	2 (1.0)	0	2 (0.5)	2 (0.4)
鼻咽頭炎	0	1 (0.5)	0	1 (0.3)	1 (0.2)
臨床検査	23 (17.6)	30 (15.3)	30 (15.5)	60 (15.4)	83 (15.9)
体重増加	13 (9.9)	13 (6.6)	11 (5.7)	24 (6.2)	37 (7.1)
血中プロラクチン増加	4 (3.1)	5 (2.6)	8 (4.1)	13 (3.3)	17 (3.3)

System Organ Class Preferred Term	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
アラニンアミノトランスフェラーゼ増加	2 (1.5)	4 (2.0)	6 (3.1)	10 (2.6)	12 (2.3)
体重減少	2 (1.5)	3 (1.5)	2 (1.0)	5 (1.3)	7 (1.3)
血中クレアチンホスホキナーゼ増加	1 (0.8)	4 (2.0)	1 (0.5)	5 (1.3)	6 (1.2)
筋骨格系および結合組織障害	4 (3.1)	9 (4.6)	11 (5.7)	20 (5.1)	24 (4.6)
筋固縮	4 (3.1)	5 (2.6)	10 (5.2)	15 (3.8)	19 (3.6)
神経系障害	28 (21.4)	45 (23.0)	58 (29.9)	103 (26.4)	131 (25.1)
アカシジア	11 (8.4)	22 (11.2)	24 (12.4)	46 (11.8)	57 (10.9)
振戦	9 (6.9)	12 (6.1)	24 (12.4)	36 (9.2)	45 (8.6)
運動緩慢	1 (0.8)	6 (3.1)	11 (5.7)	17 (4.4)	18 (3.5)
頭痛	4 (3.1)	7 (3.6)	5 (2.6)	12 (3.1)	16 (3.1)
ジスキネジア	2 (1.5)	5 (2.6)	7 (3.6)	12 (3.1)	14 (2.7)
浮動性めまい	2 (1.5)	5 (2.6)	3 (1.5)	8 (2.1)	10 (1.9)
傾眠	2 (1.5)	5 (2.6)	3 (1.5)	8 (2.1)	10 (1.9)
精神障害	14 (10.7)	31 (15.8)	29 (14.9)	60 (15.4)	74 (14.2)
統合失調症	4 (3.1)	10 (5.1)	5 (2.6)	15 (3.8)	19 (3.6)
不眠症	1 (0.8)	8 (4.1)	9 (4.6)	17 (4.4)	18 (3.5)
精神病性障害	3 (2.3)	6 (3.1)	0	6 (1.5)	9 (1.7)
激越	0	2 (1.0)	5 (2.6)	7 (1.8)	7 (1.3)
不安	0	2 (1.0)	3 (1.5)	5 (1.3)	5 (1.0)
血管障害	6 (4.6)	2 (1.0)	3 (1.5)	5 (1.3)	11 (2.1)
高血圧	5 (3.8)	1 (0.5)	3 (1.5)	4 (1.0)	9 (1.7)

System Organ Class Preferred Term	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)

Treatment emergent adverse events (TEAE) in the DSP-5423P treatment period are defined as events with start date on or after the initial application date of DSP-5423P and up to 17 days after the final application date of DSP-5423P over the DSP-5423P treatment period. TEAEs are coded by MedDRA version 19.1. If a subject experienced more than one episode of TEAE within a preferred term (PT) or a system organ class (SOC), the subject is counted only once in the PT or the SOC. The denominator of percentages is the number of subjects in the DSP-5423P dosed population. Treatment-related TEAE is TEAE with causality of definite, probably related, and possibly related. The final data at Open-Week 52 was used.

Control No:<<t51-aesocpt-related-d20d.sas, 2018-11-15T12:22:30>>

表2.7.4.7-19　重症度別有害事象の発現割合（20試験・ロナセンテープ貼付期、Open-52週）

20試験 DSP-5423P Dosed Population

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Subjects with any TEAE	95 (72.5)	161 (82.1)	165 (85.1)	326 (83.6)	421 (80.8)
Mild	46 (35.1)	83 (42.3)	86 (44.3)	169 (43.3)	215 (41.3)
Moderate	41 (31.3)	64 (32.7)	59 (30.4)	123 (31.5)	164 (31.5)
Severe	8 (6.1)	14 (7.1)	20 (10.3)	34 (8.7)	42 (8.1)
血液およびリンパ系障害	0	4 (2.0)	1 (0.5)	5 (1.3)	5 (1.0)
貧血	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
欠乏性貧血	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
好酸球増加症	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
鉄欠乏性貧血	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
白血球増加症	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
白血球減少症	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
心臓障害	4 (3.1)	6 (3.1)	5 (2.6)	11 (2.8)	15 (2.9)
徐脈	2 (1.5)	1 (0.5)	1 (0.5)	2 (0.5)	4 (0.8)
Mild	2 (1.5)	1 (0.5)	1 (0.5)	2 (0.5)	4 (0.8)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
洞性徐脈	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.6)
Mild	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
動悸	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Mild	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
頻脈	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
急性心筋梗塞	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)	1 (0.2)
第二度房室ブロック	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
右脚ブロック	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
心室内伝導障害	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
心筋虚血	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
耳および迷路障害	0	2 (1.0)	0	2 (0.5)	2 (0.4)
耳垢栓塞	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
乗物酔い	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
内分泌障害	3 (2.3)	6 (3.1)	4 (2.1)	10 (2.6)	13 (2.5)
高プロラクチン血症	3 (2.3)	6 (3.1)	4 (2.1)	10 (2.6)	13 (2.5)
Mild	3 (2.3)	6 (3.1)	3 (1.5)	9 (2.3)	12 (2.3)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
眼障害	4 (3.1)	8 (4.1)	8 (4.1)	16 (4.1)	20 (3.8)
眼乾燥	0	1 (0.5)	3 (1.5)	4 (1.0)	4 (0.8)
Mild	0	1 (0.5)	3 (1.5)	4 (1.0)	4 (0.8)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
白内障	1 (0.8)	1 (0.5)	1 (0.5)	2 (0.5)	3 (0.6)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
眼球回転発作	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
眼瞼炎	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
結膜出血	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
結膜充血	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
アレルギー性結膜炎	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
複視	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
眼脂	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
眼部腫脹	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
眼瞼浮腫	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
遠視	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
涙液分泌低下	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
流涙増加	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
近視	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
眼充血	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
霧視	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
胃腸障害	20 (15.3)	39 (19.9)	54 (27.8)	93 (23.8)	113 (21.7)
便秘	6 (4.6)	8 (4.1)	13 (6.7)	21 (5.4)	27 (5.2)
Mild	6 (4.6)	8 (4.1)	13 (6.7)	21 (5.4)	27 (5.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
流涎過多	3 (2.3)	5 (2.6)	10 (5.2)	15 (3.8)	18 (3.5)
Mild	3 (2.3)	4 (2.0)	9 (4.6)	13 (3.3)	16 (3.1)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Moderate	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Severe	0	0	0	0	0
歯痛	3 (2.3)	6 (3.1)	5 (2.6)	11 (2.8)	14 (2.7)
Mild	3 (2.3)	6 (3.1)	5 (2.6)	11 (2.8)	14 (2.7)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
下痢	2 (1.5)	2 (1.0)	9 (4.6)	11 (2.8)	13 (2.5)
Mild	2 (1.5)	1 (0.5)	9 (4.6)	10 (2.6)	12 (2.3)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
嘔吐	0	6 (3.1)	6 (3.1)	12 (3.1)	12 (2.3)
Mild	0	4 (2.0)	5 (2.6)	9 (2.3)	9 (1.7)
Moderate	0	2 (1.0)	1 (0.5)	3 (0.8)	3 (0.6)
Severe	0	0	0	0	0
齲歯	4 (3.1)	3 (1.5)	3 (1.5)	6 (1.5)	10 (1.9)
Mild	4 (3.1)	2 (1.0)	3 (1.5)	5 (1.3)	9 (1.7)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
悪心	1 (0.8)	5 (2.6)	4 (2.1)	9 (2.3)	10 (1.9)
Mild	1 (0.8)	5 (2.6)	3 (1.5)	8 (2.1)	9 (1.7)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
胃炎	3 (2.3)	1 (0.5)	4 (2.1)	5 (1.3)	8 (1.5)
Mild	3 (2.3)	1 (0.5)	4 (2.1)	5 (1.3)	8 (1.5)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
腹痛	1 (0.8)	1 (0.5)	3 (1.5)	4 (1.0)	5 (1.0)
Mild	0	1 (0.5)	3 (1.5)	4 (1.0)	4 (0.8)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
上腹部痛	2 (1.5)	2 (1.0)	1 (0.5)	3 (0.8)	5 (1.0)
Mild	2 (1.5)	2 (1.0)	1 (0.5)	3 (0.8)	5 (1.0)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
腹部不快感	1 (0.8)	2 (1.0)	0	2 (0.5)	3 (0.6)
Mild	1 (0.8)	2 (1.0)	0	2 (0.5)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
消化不良	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Mild	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
腹部膨満	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Severe	0	0	0	0	0
裂肛	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
慢性胃炎	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
大腸炎	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)	1 (0.2)
口内乾燥	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
嚥下障害	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
胃潰瘍	0	1 (0.5)	0	1 (0.3)	1 (0.2)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
胃食道逆流性疾患	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
血便排泄	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
痔核	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
口唇出血	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
口腔内潰瘍形成	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
非感染性歯肉炎	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
口腔内不快感	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
舌突出	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
口内炎	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
舌障害	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
上部消化管出血	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
一般・全身障害および投与部位の状態	23 (17.6)	46 (23.5)	66 (34.0)	112 (28.7)	135 (25.9)
適用部位紅斑	8 (6.1)	12 (6.1)	23 (11.9)	35 (9.0)	43 (8.3)
Mild	8 (6.1)	10 (5.1)	20 (10.3)	30 (7.7)	38 (7.3)
Moderate	0	2 (1.0)	3 (1.5)	5 (1.3)	5 (1.0)
Severe	0	0	0	0	0
適用部位そう痒感	4 (3.1)	14 (7.1)	19 (9.8)	33 (8.5)	37 (7.1)
Mild	3 (2.3)	14 (7.1)	17 (8.8)	31 (7.9)	34 (6.5)
Moderate	1 (0.8)	0	2 (1.0)	2 (0.5)	3 (0.6)
Severe	0	0	0	0	0
適用部位皮膚炎	2 (1.5)	4 (2.0)	6 (3.1)	10 (2.6)	12 (2.3)
Mild	1 (0.8)	4 (2.0)	5 (2.6)	9 (2.3)	10 (1.9)
Moderate	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Severe	0	0	0	0	0
発熱	3 (2.3)	3 (1.5)	4 (2.1)	7 (1.8)	10 (1.9)
Mild	3 (2.3)	2 (1.0)	4 (2.1)	6 (1.5)	9 (1.7)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
無力症	0	6 (3.1)	3 (1.5)	9 (2.3)	9 (1.7)
Mild	0	6 (3.1)	2 (1.0)	8 (2.1)	8 (1.5)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
歩行障害	1 (0.8)	2 (1.0)	6 (3.1)	8 (2.1)	9 (1.7)
Mild	1 (0.8)	1 (0.5)	3 (1.5)	4 (1.0)	5 (1.0)
Moderate	0	1 (0.5)	3 (1.5)	4 (1.0)	4 (0.8)
Severe	0	0	0	0	0
適用部位刺激感	1 (0.8)	2 (1.0)	2 (1.0)	4 (1.0)	5 (1.0)
Mild	1 (0.8)	2 (1.0)	2 (1.0)	4 (1.0)	5 (1.0)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
倦怠感	0	2 (1.0)	3 (1.5)	5 (1.3)	5 (1.0)
Mild	0	2 (1.0)	2 (1.0)	4 (1.0)	4 (0.8)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
適用部位湿疹	1 (0.8)	1 (0.5)	2 (1.0)	3 (0.8)	4 (0.8)
Mild	1 (0.8)	1 (0.5)	2 (1.0)	3 (0.8)	4 (0.8)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
胸部不快感	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.6)
Mild	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
適用部位びらん	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Mild	0	2 (1.0)	0	2 (0.5)	2 (0.4)

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Moderate	0	0	0	0	0
Severe	0	0	0	0	0
適用部位発疹	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Mild	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
適用部位小水疱	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Mild	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
疲労	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
非心臓性胸痛	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
末梢性浮腫	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Mild	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

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末梢腫脹	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
適用部位ざ瘡	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
適用部位変色	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
適用部位乾燥	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
適用部位丘疹	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
適用部位反応	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0

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Severe	0	0	0	0	0
胸痛	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
死亡	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)	1 (0.2)
熱感	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
高熱	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
浮腫	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
疼痛	0	1 (0.5)	0	1 (0.3)	1 (0.2)

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Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
突然死	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	1 (0.8)	0	0	0	1 (0.2)
肝胆道系障害	5 (3.8)	5 (2.6)	2 (1.0)	7 (1.8)	12 (2.3)
肝機能異常	2 (1.5)	2 (1.0)	0	2 (0.5)	4 (0.8)
Mild	2 (1.5)	1 (0.5)	0	1 (0.3)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)	1 (0.2)
慢性胆嚢炎	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Mild	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
肝障害	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)	1 (0.2)
胆管結石	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0

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Severe	0	0	1 (0.5)	1 (0.3)	1 (0.2)
胆嚢ポリープ	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
肝硬変	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
肝嚢胞	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
脂肪肝	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
免疫系障害	0	0	2 (1.0)	2 (0.5)	2 (0.4)
食物アレルギー	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

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季節性アレルギー	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
感染症および寄生虫症	33 (25.2)	51 (26.0)	51 (26.3)	102 (26.2)	135 (25.9)
鼻咽頭炎	11 (8.4)	14 (7.1)	25 (12.9)	39 (10.0)	50 (9.6)
Mild	9 (6.9)	11 (5.6)	21 (10.8)	32 (8.2)	41 (7.9)
Moderate	2 (1.5)	3 (1.5)	4 (2.1)	7 (1.8)	9 (1.7)
Severe	0	0	0	0	0
上気道感染	7 (5.3)	11 (5.6)	5 (2.6)	16 (4.1)	23 (4.4)
Mild	7 (5.3)	11 (5.6)	4 (2.1)	15 (3.8)	22 (4.2)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
インフルエンザ	0	4 (2.0)	3 (1.5)	7 (1.8)	7 (1.3)
Mild	0	3 (1.5)	3 (1.5)	6 (1.5)	6 (1.2)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
結膜炎	1 (0.8)	3 (1.5)	2 (1.0)	5 (1.3)	6 (1.2)
Mild	1 (0.8)	3 (1.5)	1 (0.5)	4 (1.0)	5 (1.0)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
咽頭炎	1 (0.8)	2 (1.0)	2 (1.0)	4 (1.0)	5 (1.0)
Mild	1 (0.8)	2 (1.0)	2 (1.0)	4 (1.0)	5 (1.0)

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Moderate	0	0	0	0	0
Severe	0	0	0	0	0
肺炎	2 (1.5)	1 (0.5)	2 (1.0)	3 (0.8)	5 (1.0)
Mild	2 (1.5)	0	0	0	2 (0.4)
Moderate	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.6)
Severe	0	0	0	0	0
胃腸炎	1 (0.8)	1 (0.5)	2 (1.0)	3 (0.8)	4 (0.8)
Mild	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.6)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
ウイルス性気道感染	2 (1.5)	2 (1.0)	0	2 (0.5)	4 (0.8)
Mild	2 (1.5)	2 (1.0)	0	2 (0.5)	4 (0.8)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
白癬感染	1 (0.8)	1 (0.5)	2 (1.0)	3 (0.8)	4 (0.8)
Mild	1 (0.8)	1 (0.5)	2 (1.0)	3 (0.8)	4 (0.8)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
蜂巣炎	2 (1.5)	0	1 (0.5)	1 (0.3)	3 (0.6)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Severe	0	0	0	0	0

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爪の皮膚糸状菌症	1 (0.8)	2 (1.0)	0	2 (0.5)	3 (0.6)
Mild	1 (0.8)	2 (1.0)	0	2 (0.5)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
皮膚真菌感染	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.6)
Mild	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
鼻炎	2 (1.5)	0	1 (0.5)	1 (0.3)	3 (0.6)
Mild	2 (1.5)	0	1 (0.5)	1 (0.3)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
体部白癬	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Mild	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
感染性湿疹	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Mild	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
せつ	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)

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Severe	0	0	0	0	0
感染性皮膚潰瘍	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
外耳炎	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Mild	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
爪囲炎	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
尿路感染	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
四肢膿瘍	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
口腔膿瘍	1 (0.8)	0	0	0	1 (0.2)

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Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
適用部位膿瘍	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
適用部位感染	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
細菌感染	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
バルトリン腺膿瘍	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
真菌感染	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
歯肉炎	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
B型肝炎	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
ヘルペス性皮膚炎	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
椎間板炎	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)	1 (0.2)
シラミ寄生	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
口唇感染	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
中耳炎	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
耳下腺炎	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
歯周炎	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
咽頭扁桃炎	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
肺結核	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0

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膿疱性皮疹	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
卵管卵巣炎	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
副鼻腔炎	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
全身性ウイルス感染	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
足部白癬	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
癤風	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0

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Severe	0	0	0	0	0
気管炎	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
膣感染	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
水痘	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
外陰部膣カンジダ症	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
ブドウ球菌性創感染	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
傷害、中毒および処置合併症	13 (9.9)	20 (10.2)	19 (9.8)	39 (10.0)	52 (10.0)

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皮膚擦過傷	3 (2.3)	4 (2.0)	4 (2.1)	8 (2.1)	11 (2.1)
Mild	2 (1.5)	4 (2.0)	4 (2.1)	8 (2.1)	10 (1.9)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
裂傷	3 (2.3)	5 (2.6)	2 (1.0)	7 (1.8)	10 (1.9)
Mild	3 (2.3)	3 (1.5)	2 (1.0)	5 (1.3)	8 (1.5)
Moderate	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Severe	0	0	0	0	0
挫傷	2 (1.5)	1 (0.5)	4 (2.1)	5 (1.3)	7 (1.3)
Mild	2 (1.5)	1 (0.5)	4 (2.1)	5 (1.3)	7 (1.3)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
擦過傷	2 (1.5)	0	3 (1.5)	3 (0.8)	5 (1.0)
Mild	2 (1.5)	0	3 (1.5)	3 (0.8)	5 (1.0)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
転倒	2 (1.5)	0	1 (0.5)	1 (0.3)	3 (0.6)
Mild	2 (1.5)	0	1 (0.5)	1 (0.3)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
軟部組織損傷	2 (1.5)	1 (0.5)	0	1 (0.3)	3 (0.6)
Mild	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Moderate	1 (0.8)	0	0	0	1 (0.2)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Severe	0	0	0	0	0
各種物質毒性	1 (0.8)	0	2 (1.0)	2 (0.5)	3 (0.6)
Mild	0	0	0	0	0
Moderate	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Severe	1 (0.8)	0	0	0	1 (0.2)
外傷性血腫	0	2 (1.0)	1 (0.5)	3 (0.8)	3 (0.6)
Mild	0	2 (1.0)	1 (0.5)	3 (0.8)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
節足動物咬傷	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Mild	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
靭帯捻挫	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Mild	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
熱傷	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
術後貧血	0	1 (0.5)	0	1 (0.3)	1 (0.2)

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Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
足関節部骨折	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
節足動物刺傷	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
鎖骨骨折	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
粉砕骨折	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
耳擦過傷	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

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経口曝露	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
眼挫傷	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
顔面骨骨折	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
大腿骨頚部骨折	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)	1 (0.2)
手骨折	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
頭部損傷	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)

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Moderate	0	0	0	0	0
Severe	0	0	0	0	0
上腕骨骨折	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
四肢損傷	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
口唇損傷	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
外傷後頚部症候群	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
肺挫傷	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)	1 (0.2)

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創傷	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
臨床検査	26 (19.8)	35 (17.9)	40 (20.6)	75 (19.2)	101 (19.4)
体重増加	16 (12.2)	13 (6.6)	13 (6.7)	26 (6.7)	42 (8.1)
Mild	10 (7.6)	11 (5.6)	10 (5.2)	21 (5.4)	31 (6.0)
Moderate	6 (4.6)	2 (1.0)	3 (1.5)	5 (1.3)	11 (2.1)
Severe	0	0	0	0	0
血中プロラクチン増加	4 (3.1)	5 (2.6)	8 (4.1)	13 (3.3)	17 (3.3)
Mild	4 (3.1)	5 (2.6)	8 (4.1)	13 (3.3)	17 (3.3)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
アラニンアミノトランスフェラーゼ増加	3 (2.3)	5 (2.6)	6 (3.1)	11 (2.8)	14 (2.7)
Mild	3 (2.3)	5 (2.6)	5 (2.6)	10 (2.6)	13 (2.5)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
体重減少	2 (1.5)	8 (4.1)	2 (1.0)	10 (2.6)	12 (2.3)
Mild	1 (0.8)	8 (4.1)	2 (1.0)	10 (2.6)	11 (2.1)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
血中クレアチンホスホキナーゼ増加	1 (0.8)	8 (4.1)	2 (1.0)	10 (2.6)	11 (2.1)
Mild	1 (0.8)	8 (4.1)	0	8 (2.1)	9 (1.7)

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Moderate	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Severe	0	0	0	0	0
血中ブドウ糖増加	2 (1.5)	2 (1.0)	6 (3.1)	8 (2.1)	10 (1.9)
Mild	1 (0.8)	2 (1.0)	4 (2.1)	6 (1.5)	7 (1.3)
Moderate	1 (0.8)	0	2 (1.0)	2 (0.5)	3 (0.6)
Severe	0	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	2 (1.5)	4 (2.0)	2 (1.0)	6 (1.5)	8 (1.5)
Mild	2 (1.5)	4 (2.0)	2 (1.0)	6 (1.5)	8 (1.5)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
γーグルタミルトランスフェラーゼ増加	1 (0.8)	3 (1.5)	3 (1.5)	6 (1.5)	7 (1.3)
Mild	1 (0.8)	3 (1.5)	3 (1.5)	6 (1.5)	7 (1.3)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
血中コレステロール増加	1 (0.8)	3 (1.5)	0	3 (0.8)	4 (0.8)
Mild	1 (0.8)	3 (1.5)	0	3 (0.8)	4 (0.8)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
血中乳酸脱水素酵素増加	1 (0.8)	1 (0.5)	1 (0.5)	2 (0.5)	3 (0.6)
Mild	1 (0.8)	1 (0.5)	1 (0.5)	2 (0.5)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

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血圧上昇	1 (0.8)	0	2 (1.0)	2 (0.5)	3 (0.6)
Mild	1 (0.8)	0	2 (1.0)	2 (0.5)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
血中トリグリセリド増加	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.6)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
肝酵素上昇	1 (0.8)	0	2 (1.0)	2 (0.5)	3 (0.6)
Mild	1 (0.8)	0	2 (1.0)	2 (0.5)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
血中アルカリホスファターゼ増加	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
血小板数減少	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Mild	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
尿中蛋白陽性	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0

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Severe	0	0	0	0	0
白血球数増加	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
血中ビリルビン増加	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
血中クレアチニン増加	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
血中ブドウ糖異常	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
血中カリウム増加	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
拡張期血圧上昇	0	0	1 (0.5)	1 (0.3)	1 (0.2)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
体温上昇	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
心電図ＳＴ部分下降	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
心電図Ｔ波振幅減少	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
心電図Ｔ波増高	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
好酸球数増加	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
グリコヘモグロビン増加	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
心拍数減少	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
リンパ球数増加	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
好中球数減少	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
好中球数増加	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
尿中ウロビリノーゲン増加	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
白血球数減少	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
代謝および栄養障害	7 (5.3)	14 (7.1)	14 (7.2)	28 (7.2)	35 (6.7)
食欲減退	2 (1.5)	5 (2.6)	2 (1.0)	7 (1.8)	9 (1.7)
Mild	2 (1.5)	5 (2.6)	2 (1.0)	7 (1.8)	9 (1.7)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
低カリウム血症	0	1 (0.5)	4 (2.1)	5 (1.3)	5 (1.0)
Mild	0	1 (0.5)	3 (1.5)	4 (1.0)	4 (0.8)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
低ナトリウム血症	1 (0.8)	3 (1.5)	1 (0.5)	4 (1.0)	5 (1.0)
Mild	1 (0.8)	2 (1.0)	0	2 (0.5)	3 (0.6)
Moderate	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Severe	0	0	0	0	0
高脂血症	0	1 (0.5)	3 (1.5)	4 (1.0)	4 (0.8)
Mild	0	1 (0.5)	3 (1.5)	4 (1.0)	4 (0.8)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
脱水	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Mild	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
糖尿病	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
高コレステロール血症	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
食欲亢進	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
拒食	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
脂質異常症	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
高血糖	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
高トリグリセリド血症	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
低血糖	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
空腹時血中ブドウ糖不良	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
過体重	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
多飲症	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
２型糖尿病	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
筋骨格系および結合組織障害	10 (7.6)	18 (9.2)	23 (11.9)	41 (10.5)	51 (9.8)
筋固縮	4 (3.1)	5 (2.6)	11 (5.7)	16 (4.1)	20 (3.8)
Mild	3 (2.3)	2 (1.0)	6 (3.1)	8 (2.1)	11 (2.1)
Moderate	1 (0.8)	3 (1.5)	5 (2.6)	8 (2.1)	9 (1.7)
Severe	0	0	0	0	0
背部痛	2 (1.5)	2 (1.0)	4 (2.1)	6 (1.5)	8 (1.5)
Mild	2 (1.5)	2 (1.0)	4 (2.1)	6 (1.5)	8 (1.5)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
筋肉痛	2 (1.5)	1 (0.5)	2 (1.0)	3 (0.8)	5 (1.0)
Mild	2 (1.5)	0	2 (1.0)	2 (0.5)	4 (0.8)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
四肢痛	1 (0.8)	3 (1.5)	1 (0.5)	4 (1.0)	5 (1.0)
Mild	1 (0.8)	2 (1.0)	1 (0.5)	3 (0.8)	4 (0.8)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
関節痛	0	2 (1.0)	1 (0.5)	3 (0.8)	3 (0.6)
Mild	0	2 (1.0)	1 (0.5)	3 (0.8)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
筋力低下	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
筋骨格系胸痛	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Mild	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
筋骨格硬直	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Mild	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
椎間板突出	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)	1 (0.2)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
関節腫脹	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
四肢不快感	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
筋痙縮	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
筋骨格痛	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
頚部痛	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
骨減少症	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0

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Severe	0	0	0	0	0
骨膜炎	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
滑液嚢腫	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.6)
脂肪腫	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
乳房脂肪腫	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
子宮平滑筋腫	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
神経系障害	31 (23.7)	51 (26.0)	71 (36.6)	122 (31.3)	153 (29.4)
アカシジア	11 (8.4)	22 (11.2)	27 (13.9)	49 (12.6)	60 (11.5)
Mild	7 (5.3)	18 (9.2)	20 (10.3)	38 (9.7)	45 (8.6)
Moderate	4 (3.1)	3 (1.5)	6 (3.1)	9 (2.3)	13 (2.5)
Severe	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
振戦	9 (6.9)	14 (7.1)	27 (13.9)	41 (10.5)	50 (9.6)
Mild	8 (6.1)	13 (6.6)	23 (11.9)	36 (9.2)	44 (8.4)
Moderate	1 (0.8)	1 (0.5)	4 (2.1)	5 (1.3)	6 (1.2)
Severe	0	0	0	0	0
頭痛	6 (4.6)	13 (6.6)	17 (8.8)	30 (7.7)	36 (6.9)
Mild	6 (4.6)	13 (6.6)	15 (7.7)	28 (7.2)	34 (6.5)
Moderate	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Severe	0	0	0	0	0
運動緩慢	1 (0.8)	6 (3.1)	11 (5.7)	17 (4.4)	18 (3.5)
Mild	1 (0.8)	5 (2.6)	7 (3.6)	12 (3.1)	13 (2.5)
Moderate	0	1 (0.5)	4 (2.1)	5 (1.3)	5 (1.0)
Severe	0	0	0	0	0
ジスキネジア	3 (2.3)	5 (2.6)	8 (4.1)	13 (3.3)	16 (3.1)
Mild	2 (1.5)	5 (2.6)	7 (3.6)	12 (3.1)	14 (2.7)
Moderate	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Severe	0	0	0	0	0
浮動性めまい	2 (1.5)	6 (3.1)	4 (2.1)	10 (2.6)	12 (2.3)
Mild	2 (1.5)	6 (3.1)	4 (2.1)	10 (2.6)	12 (2.3)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
傾眠	3 (2.3)	5 (2.6)	4 (2.1)	9 (2.3)	12 (2.3)
Mild	3 (2.3)	4 (2.0)	3 (1.5)	7 (1.8)	10 (1.9)
Moderate	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Severe	0	0	0	0	0
ジストニア	2 (1.5)	2 (1.0)	4 (2.1)	6 (1.5)	8 (1.5)
Mild	1 (0.8)	2 (1.0)	2 (1.0)	4 (1.0)	5 (1.0)
Moderate	1 (0.8)	0	2 (1.0)	2 (0.5)	3 (0.6)
Severe	0	0	0	0	0
睡眠の質低下	1 (0.8)	0	2 (1.0)	2 (0.5)	3 (0.6)
Mild	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
全身性強直性間代性発作	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	1 (0.5)	0	1 (0.3)	1 (0.2)
パーキンソン歩行	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Mild	0	0	0	0	0
Moderate	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
無動	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
体位性めまい	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
よだれ	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
構語障害	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
顔面不全麻痺	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
ギラン・バレー症候群	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Severe	0	0	1 (0.5)	1 (0.3)	1 (0.2)
過眠症	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
筋緊張亢進	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
感覚鈍麻	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
運動障害	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
精神運動亢進	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
表情減少	0	0	1 (0.5)	1 (0.3)	1 (0.2)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
安静時振戦	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
鎮静	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
失神	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
精神障害	28 (21.4)	73 (37.2)	59 (30.4)	132 (33.8)	160 (30.7)
統合失調症	12 (9.2)	22 (11.2)	14 (7.2)	36 (9.2)	48 (9.2)
Mild	3 (2.3)	1 (0.5)	1 (0.5)	2 (0.5)	5 (1.0)
Moderate	8 (6.1)	16 (8.2)	5 (2.6)	21 (5.4)	29 (5.6)
Severe	1 (0.8)	5 (2.6)	8 (4.1)	13 (3.3)	14 (2.7)
不眠症	5 (3.8)	22 (11.2)	20 (10.3)	42 (10.8)	47 (9.0)
Mild	2 (1.5)	17 (8.7)	13 (6.7)	30 (7.7)	32 (6.1)
Moderate	3 (2.3)	5 (2.6)	7 (3.6)	12 (3.1)	15 (2.9)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Severe	0	0	0	0	0
精神病性障害	7 (5.3)	11 (5.6)	5 (2.6)	16 (4.1)	23 (4.4)
Mild	1 (0.8)	1 (0.5)	1 (0.5)	2 (0.5)	3 (0.6)
Moderate	4 (3.1)	8 (4.1)	4 (2.1)	12 (3.1)	16 (3.1)
Severe	2 (1.5)	2 (1.0)	0	2 (0.5)	4 (0.8)
激越	2 (1.5)	9 (4.6)	8 (4.1)	17 (4.4)	19 (3.6)
Mild	0	6 (3.1)	6 (3.1)	12 (3.1)	12 (2.3)
Moderate	2 (1.5)	3 (1.5)	2 (1.0)	5 (1.3)	7 (1.3)
Severe	0	0	0	0	0
不安	0	7 (3.6)	6 (3.1)	13 (3.3)	13 (2.5)
Mild	0	4 (2.0)	2 (1.0)	6 (1.5)	6 (1.2)
Moderate	0	3 (1.5)	4 (2.1)	7 (1.8)	7 (1.3)
Severe	0	0	0	0	0
易刺激性	3 (2.3)	2 (1.0)	5 (2.6)	7 (1.8)	10 (1.9)
Mild	3 (2.3)	2 (1.0)	3 (1.5)	5 (1.3)	8 (1.5)
Moderate	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Severe	0	0	0	0	0
攻撃性	1 (0.8)	4 (2.0)	4 (2.1)	8 (2.1)	9 (1.7)
Mild	0	3 (1.5)	2 (1.0)	5 (1.3)	5 (1.0)
Moderate	1 (0.8)	1 (0.5)	2 (1.0)	3 (0.8)	4 (0.8)
Severe	0	0	0	0	0
自殺念慮	1 (0.8)	7 (3.6)	1 (0.5)	8 (2.1)	9 (1.7)

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Mild	0	5 (2.6)	1 (0.5)	6 (1.5)	6 (1.2)
Moderate	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Severe	1 (0.8)	0	0	0	1 (0.2)
落ち着きのなさ	3 (2.3)	4 (2.0)	1 (0.5)	5 (1.3)	8 (1.5)
Mild	2 (1.5)	4 (2.0)	1 (0.5)	5 (1.3)	7 (1.3)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
精神症状	2 (1.5)	2 (1.0)	3 (1.5)	5 (1.3)	7 (1.3)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	1 (0.8)	0	2 (1.0)	2 (0.5)	3 (0.6)
Severe	1 (0.8)	1 (0.5)	1 (0.5)	2 (0.5)	3 (0.6)
衝動行為	1 (0.8)	2 (1.0)	1 (0.5)	3 (0.8)	4 (0.8)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Severe	0	0	0	0	0
異常行動	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.6)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Severe	0	0	0	0	0
睡眠障害	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

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自殺企図	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)	1 (0.2)
異常な夢	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
不安障害	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
カタトニー	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	1 (0.8)	0	0	0	1 (0.2)
自殺既遂	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)	1 (0.2)
妄想	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0

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Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
抑うつ気分	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
幻覚	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)	1 (0.2)
幻視	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
敵意	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
初期不眠症	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

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悪夢	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
心因性呼吸窮迫	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
精神病的行動	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
不適切な性的行動	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)	1 (0.2)
腎および尿路障害	2 (1.5)	5 (2.6)	5 (2.6)	10 (2.6)	12 (2.3)
排尿困難	0	2 (1.0)	2 (1.0)	4 (1.0)	4 (0.8)
Mild	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.6)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
頻尿	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)

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Moderate	0	0	0	0	0
Severe	0	0	0	0	0
蛋白尿	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
糖尿	1 (0.8)	0	0	0	1 (0.2)
Mild	0	0	0	0	0
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
血尿	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
失禁	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
腎嚢胞	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

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腹圧性尿失禁	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
生殖系および乳房障害	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.6)
月経困難症	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
不規則月経	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
陰部そう痒症	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
呼吸器、胸郭および縦隔障害	8 (6.1)	11 (5.6)	17 (8.8)	28 (7.2)	36 (6.9)
咳嗽	3 (2.3)	3 (1.5)	6 (3.1)	9 (2.3)	12 (2.3)
Mild	2 (1.5)	3 (1.5)	6 (3.1)	9 (2.3)	11 (2.1)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
口腔咽頭痛	1 (0.8)	1 (0.5)	2 (1.0)	3 (0.8)	4 (0.8)

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Mild	1 (0.8)	1 (0.5)	2 (1.0)	3 (0.8)	4 (0.8)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
鼻出血	0	2 (1.0)	1 (0.5)	3 (0.8)	3 (0.6)
Mild	0	2 (1.0)	1 (0.5)	3 (0.8)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
アレルギー性鼻炎	1 (0.8)	1 (0.5)	1 (0.5)	2 (0.5)	3 (0.6)
Mild	1 (0.8)	1 (0.5)	1 (0.5)	2 (0.5)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
鼻漏	1 (0.8)	2 (1.0)	0	2 (0.5)	3 (0.6)
Mild	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
慢性気管支炎	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Mild	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
呼吸障害	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Mild	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

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喘息	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
気管支痙攣	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
息詰まり	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)	1 (0.2)
鼻閉	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
誤嚥性肺炎	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
湿性咳嗽	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)

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Moderate	0	0	0	0	0
Severe	0	0	0	0	0
肺塞栓症	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)	1 (0.2)
上気道の炎症	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
皮膚および皮下組織障害	9 (6.9)	31 (15.8)	29 (14.9)	60 (15.4)	69 (13.2)
湿疹	1 (0.8)	8 (4.1)	2 (1.0)	10 (2.6)	11 (2.1)
Mild	0	8 (4.1)	2 (1.0)	10 (2.6)	10 (1.9)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
そう痒症	0	4 (2.0)	6 (3.1)	10 (2.6)	10 (1.9)
Mild	0	4 (2.0)	6 (3.1)	10 (2.6)	10 (1.9)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
皮膚炎	1 (0.8)	4 (2.0)	2 (1.0)	6 (1.5)	7 (1.3)
Mild	1 (0.8)	4 (2.0)	2 (1.0)	6 (1.5)	7 (1.3)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
皮膚乾燥	1 (0.8)	1 (0.5)	5 (2.6)	6 (1.5)	7 (1.3)
Mild	1 (0.8)	1 (0.5)	5 (2.6)	6 (1.5)	7 (1.3)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
発疹	1 (0.8)	4 (2.0)	2 (1.0)	6 (1.5)	7 (1.3)
Mild	1 (0.8)	4 (2.0)	1 (0.5)	5 (1.3)	6 (1.2)
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
過角化	0	0	3 (1.5)	3 (0.8)	3 (0.6)
Mild	0	0	3 (1.5)	3 (0.8)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
顔面腫脹	1 (0.8)	0	2 (1.0)	2 (0.5)	3 (0.6)
Mild	1 (0.8)	0	2 (1.0)	2 (0.5)	3 (0.6)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
皮脂欠乏性湿疹	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
汗疹	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
皮膚潰瘍	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Mild	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
蕁麻疹	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Mild	1 (0.8)	0	1 (0.5)	1 (0.3)	2 (0.4)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
ざ瘡	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
皮膚嚢腫	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
アレルギー性皮膚炎	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
接触皮膚炎	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
薬疹	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
皮下出血	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
多汗症	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
嵌入爪	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
間擦疹	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Severe	0	0	0	0	0
爪肥厚	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
光線過敏性反応	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
全身性そう痒症	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
乾癬	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
全身性皮疹	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
斑状丘疹状皮疹	0	1 (0.5)	0	1 (0.3)	1 (0.2)

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
そう痒性皮疹	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
脂漏性皮膚炎	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
皮膚亀裂	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
皮膚刺激	1 (0.8)	0	0	0	1 (0.2)
Mild	1 (0.8)	0	0	0	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
社会環境	0	0	1 (0.5)	1 (0.3)	1 (0.2)
社会的入院	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Mild	0	0	1 (0.5)	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
Severe	0	0	0	0	0
血管障害	8 (6.1)	9 (4.6)	7 (3.6)	16 (4.1)	24 (4.6)
高血圧	6 (4.6)	3 (1.5)	5 (2.6)	8 (2.1)	14 (2.7)
Mild	5 (3.8)	0	4 (2.1)	4 (1.0)	9 (1.7)
Moderate	1 (0.8)	3 (1.5)	1 (0.5)	4 (1.0)	5 (1.0)
Severe	0	0	0	0	0
低血圧	1 (0.8)	1 (0.5)	2 (1.0)	3 (0.8)	4 (0.8)
Mild	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Moderate	0	0	2 (1.0)	2 (0.5)	2 (0.4)
Severe	0	0	0	0	0
本態性高血圧症	1 (0.8)	1 (0.5)	0	1 (0.3)	2 (0.4)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	1 (0.8)	0	0	0	1 (0.2)
Severe	0	0	0	0	0
血腫	0	2 (1.0)	0	2 (0.5)	2 (0.4)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Severe	0	0	0	0	0
動脈硬化症	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

System Organ Class Preferred Term Maximum Severity	PLCB-to-FLEX DOSE (N = 131) n (%)	40MG-to-FLEX DOSE (N = 196) n (%)	80MG-to-FLEX DOSE (N = 194) n (%)	Active-to-FLEX DOSE (N = 390) n (%)	Overall-to-FLEX DOSE (N = 521) n (%)
出血	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0
高血圧クリーゼ	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Mild	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Moderate	0	0	0	0	0
Severe	0	0	0	0	0

Treatment emergent adverse events (TEAE) in the DSP-5423P treatment period are defined as events with start date on or after the initial application date of DSP-5423P and up to 17 days after the final application date of DSP-5423P over the DSP-5423P treatment period. TEAEs are coded by MedDRA version 19.1. If a subject experienced more than one episode of TEAE within a preferred term (PT), the subject is counted only once in the PT for the maximum severity. The denominator of percentages is the number of subjects in the DSP-5423P dosed population. The final data at Open-Week 52 was used.

Control No:<<t55-aesocpt-sev-d20d.sas, 2018-11-15T12:22:48>>

表2.7.4.7-20　重篤な有害事象の一覧（20試験・ロナセンテープ貼付期、Open-52週）
All Patients

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]01/ 5[redacted]/ F/ JPN	3	Nervous system disorders/ 神経系障害 Generalised tonic-clonic seizure/ 全身性強直性間代性発作 Tonic-clonic convulsions	(20) (21) 2 Double-blind treatment phase 40 mg/day	SEVERE/ POSSIBLE/ Y (Other medically important event)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 5[redacted]/ F/ JPN	516	Injury, poisoning and procedural complications/ 傷害、中毒および処置合併症 Femoral neck fracture/ 大腿骨頸部骨折 right femoral neck fracture	(321) ONGOING - Open-label treatment phase 60 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 4[redacted]/ F/ JPN	502	Infections and infestations/ 感染症および寄生虫症 Bartholin's abscess/ バルトリン腺腫瘍 Bartholin`s abscess	(226) (227) 2 Open-label treatment phase 60 mg/day	MILD/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
		507	Musculoskeletal and connective tissue disorders/ 筋骨格系および結合組織障害 Intervertebral disc protrusion/ 椎間板突出 Worsening of Lumbar disc hernia	(421) (439) 19 Follow-up phase 60 mg/day *	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ NOT APPLICABLE
[redacted]	1[redacted]01/ 4[redacted]/ M/ JPN	1	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Aggravation of schizophrenia	(14) ONGOING - Double-blind treatment phase 40 mg/day *	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
	1[redacted]10/ 4[redacted]/ M/ JPN	501	Nervous system disorders/ 神経系障害 Akathisia/アカシジア akathisia	(81) (93) 13 Open-label treatment phase 80 mg/day	SEVERE/ DEFINITE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
[redacted]	1[redacted]03/ 2[redacted]/ F/ JPN	506	Psychiatric disorders/ 精神障害 Suicidal ideation/ 自殺念慮 suicidal idea	(179) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]07/ 6[redacted]/ F/ JPN	3	Injury, poisoning and procedural complications/ 傷害、中毒および処置合併症 Humerus fracture/ 上腕骨骨折 fracture of humerus	(16) ONGOING - Double-blind treatment phase 40 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DOSE NOT CHANGED
[redacted]	1[redacted]03/ 6[redacted]/ F/ JPN	502	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 recurrence of schizophrenia	(425) ONGOING - Follow-up phase 80 mg/day *	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ NOT APPLICABLE
[redacted]	2[redacted]07/ 3[redacted]/ M/ KOR	6	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of Schizophrenia	(26) (32) 7 Double-blind treatment phase 40 mg/day	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]01/ 3[redacted]/ F/ KOR	1	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of schizophrenia	(-2) ONGOING - Washout phase 0 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	2[redacted]02/ 2[redacted]/ F/ KOR	5	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of schizophrenia	(24) ONGOING - Double-blind treatment phase 40 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DOSE NOT CHANGED
[redacted]	3[redacted]01/ 3[redacted]/ M/ TWN	503	Nervous system disorders/ 神経系障害 Akathisia/アカシジア Akathisia	(75) (89) 15 Open-label treatment phase 80 mg/day	MODERATE/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
	3[redacted]11/ 3[redacted]/ M/ TWN	505	Psychiatric disorders/ 精神障害 Suicide attempt/ 自殺企図 Sucide attempt	(146) ONGOING - Open-label treatment phase 80 mg/day *	MILD/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
	3[redacted]16/ 4[redacted]/ M/ TWN	502	Injury, poisoning and procedural complications/ 傷害、中毒および処置合併症 Comminuted fracture/ 粉砕骨折 LEFT CLAVICULAR COMMINUTED FRACTURE	(78) (82) 5 Open-label treatment phase 40 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
[redacted]	3[redacted]01/ 3[redacted]/ M/ TWN	502	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Schizophrenic disorder	(51) (83) 33 Open-label treatment phase 60 mg/day *	MODERATE/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ NOT APPLICABLE
[redacted]	4[redacted]19/ 2[redacted]/ M/ MYS	504	Psychiatric disorders/ 精神障害 Suicidal ideation/ 自殺念慮 Suicidal Ideations	(146) (148) 3 Follow-up phase 60 mg/day *	MILD/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ NOT APPLICABLE

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	4[redacted]24/ 3[redacted]/ M/ MYS	1	Psychiatric disorders/ 精神障害 Psychotic disorder/ 精神病性障害 Exacerbation of psychosis	(31) ONGOING - Double-blind treatment phase 40 mg/day	SEVERE/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	4[redacted]02/ 4[redacted]/ M/ MYS	502	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Relapse of Schizophrenia	(135) (157) 23 Open-label treatment phase 40 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERED/RESOLVED/ DOSE INCREASED
	4[redacted]13/ 2[redacted]/ M/ MYS	501	Psychiatric disorders/精神障害 Schizophrenia/ 統合失調症 Schizophrenia (Worsening of symptoms)	(49) (85) 37 Open-label treatment phase 60 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
		505	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of Schizophrenia	(167) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERING/RESOLVING/ DOSE NOT CHANGED
[redacted]	4[redacted]20/ 2[redacted]/ F/ MYS	1	Psychiatric disorders/ 精神障害 Psychiatric symptom/ 精神症状 Exacerbation of Psychiatric Symptom.	(15) (20) 6 Double-blind treatment phase 40 mg/day	MILD/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
	4[redacted]28/ 3[redacted]/ M/ MYS	501	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Relapse Schizophrenia	(165) (205) 41 Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ Y (Requires or prolongs hospitalization, Results in persistent or significant disability/incapacity)	RECOVERED/RESOLVED/ DOSE NOT CHANGED

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	4[redacted]01/ 2[redacted]/ M/ MYS	1	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of Schizophrenia	(30) ONGOING - Double-blind treatment phase 40 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DOSE NOT CHANGED
[redacted]	4[redacted]02/ 2[redacted]/ M/ MYS	501	Psychiatric disorders/ 精神障害 Psychotic disorder/ 精神病性障害 Exacerbation of the psychotic symptoms	(46) (64) 19 Open-label treatment phase 40 mg/day	MODERATE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE INCREASED
[redacted]	5[redacted]06/ 4[redacted]/ M/ PHL	513	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Schizophrenia, in relapse	(185) (198) 14 Open-label treatment phase 40 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED WITH SEQUELAE/ DOSE NOT CHANGED
[redacted]	7[redacted]06/ 3[redacted]/ M/ RUS	503	Psychiatric disorders/ 精神障害 Psychiatric symptom/ 精神症状 Worsening of psychic state	(48) (73) 26 Open-label treatment phase 40 mg/day	MODERATE/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE INCREASED
		512	Psychiatric disorders/ 精神障害 Psychiatric symptom/ 精神症状 Worsening of psychic state	(175) (215) 41 Open-label treatment phase 80 mg/day	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]03/ 3[redacted] M/ JPN	502	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Schizophrenia aggravated	(156) ONGOING - Open-label treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 3[redacted] M/ JPN	516	Hepatobiliary disorders/ 肝胆道系障害 Bile duct stone/ 胆管結石 Common bile duct stone	(239) (350) 112 Open-label treatment phase 40 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
[redacted]	1[redacted]03/ 5[redacted] F/ JPN	511	Psychiatric disorders/ 精神障害 Hallucination/ 幻覚 worsening of Hallucination	(270) ONGOING - Open-label treatment phase 80 mg/day *	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 4[redacted] F/ JPN	512	Psychiatric disorders/ 精神障害 Psychiatric symptom/ 精神症状 Worsening of psychiatric symptom	(356) ONGOING - Open-label treatment phase 40 mg/day *	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 5[redacted] F/ JPN	1	Respiratory, thoracic and mediastinal disorders/ 呼吸器、胸郭および縦隔障害 Choking/ 息詰まり Choked on food	(9) (9) 1 Double-blind treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Life threatening)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
[redacted]	1[redacted]02/ 5[redacted] M/ JPN	504	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Schizophrenia aggravated	(261) (351) 91 Open-label treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]04/ 2[redacted]/ F/ JPN	501	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of Schizophrenia	(74) (92) 19 Open-label treatment phase 60 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]04/ 2[redacted]/ F/ JPN	505	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Schizophrenia aggrevated	(47) ONGOING - Open-label treatment phase 40 mg/day *	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	1[redacted]06/ 5[redacted]/ F/ JPN	503	Infections and infestations/ 感染症および寄生虫症 Intervertebral discitis/ 椎間板炎 Purulent diskitis	(292) (554) 263 Open-label treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]01/ 3[redacted]/ M/ KOR	2	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of schizophrenia	(7) (40) 34 Double-blind treatment phase 80 mg/day	SEVERE/ DEFINITE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]04/ 5[redacted]/ F/ KOR	512	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of Schizoprenia	(87) ONGOING - Follow-up phase 80 mg/day *	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ NOT APPLICABLE
[redacted]	4[redacted]08/ 2[redacted]/ M/ MYS	1	Psychiatric disorders/ 精神障害 Suicide attempt/ 自殺企図 Suicidal attempt	(22) (31) 10 Double-blind treatment phase 80 mg/day *	SEVERE/ PROBABLE/ Y (Life threatening, Requires or prolongs hospitalization)	RECOVERED/RESOLVED WITH SEQUELAE/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	4[redacted]12/ 6[redacted]/ M/ MYS	503	Vascular disorders/ 血管障害 Hypotension/ 低血圧 HYPOTENSION	(67) (68) 2 Open-label treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Other medically important event)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
[redacted]	4[redacted]12/ 6[redacted]/ M/ MYS	1	Infections and infestations/ 感染症および寄生虫症 Pneumonia/ 肺炎 Pneumonia	(5) (12) 8 Double-blind treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Other medically important event)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]18/ 4[redacted]/ M/ MYS	1	Cardiac disorders/ 心臓障害 Acute myocardial infarction/ 急性心筋梗塞 Cardiogenic shock secondary to NSTEMI	(35) (36) 2 Double-blind treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Results in death, Requires or prolongs hospitalization)	FATAL/ DRUG WITHDRAWN
	4[redacted]25/ 4[redacted]/ M/ MYS	501	Gastrointestinal disorders/ 胃腸障害 Colitis/ 大腸炎 Colitis	(71) (71) 1 Open-label treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Results in death)	FATAL/ DRUG WITHDRAWN
[redacted]	4[redacted]08/ 3[redacted]/ M/ MYS	1	Nervous system disorders/ 神経系障害 Guillain-Barre syndrome/ ギラン・バレー症候群 GUILLAIN BARRE SYNDROME	(3) ONGOING - Double-blind treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Results in persistent or significant disability/incapacity)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]01/ 3[redacted]/ M/ MYS	501	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Schizophrenia - Relapse	(70) (106) 37 Open-label treatment phase 40 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
		502	Injury, poisoning and procedural complications/ 傷害、中毒および処置合併症 Toxicity to various agents/ 各種物質毒性 Cannabis Intoxication	(220) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERING/RESOLVING/ DOSE NOT CHANGED
	4[redacted]06/ 4[redacted]/ M/ MYS	501	Injury, poisoning and procedural complications/ 傷害、中毒および処置合併症 Toxicity to various agents/ 各種物質毒性 Drug Intoxication	(149) (168) 20 Open-label treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
[redacted]	4[redacted]13/ 1[redacted]/ M/ MYS	503	Psychiatric disorders/ 精神障害 Abnormal behavior/ 異常行動 Worsening of behavioral problem.	(107) (109) 3 Open-label treatment phase 80 mg/day	MILD/ PROBABLE/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
	4[redacted]27/ 3[redacted]/ M/ MYS	502	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Relapse due to probable non compliance	(83) (90) 8 Open-label treatment phase 80 mg/day	MILD/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
		503	Psychiatric disorders/ 精神障害 Aggression/ 攻撃性 Aggressive Behavior (Relapse) due to Probable Non Compliance	(160) (177) 18 Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
[redacted]	4[redacted]04/ 2[redacted]/ M/ MYS	2	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of schizophrenia	(39) ONGOING - Double-blind treatment phase 80 mg/day	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERING/RESOLVING/ DOSE NOT CHANGED

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
		501 (2)	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of schizophrenia	(39) (98) 60 Double-blind treatment phase 80 mg/day	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
		502	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of schizophrenia symptoms	(134) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ PROBABLE/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	4[redacted]01/ 3[redacted]/ M/ MYS	511	Respiratory, thoracic and mediastinal disorders/ 呼吸器、胸郭および縦隔障害 Asthma/喘息 Acute exacerbation of bronchial asthma	(150) (154) 5 Open-label treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
[redacted]	4[redacted]07/ 2[redacted]/ F/ MYS	501	Social circumstances/ 社会環境 Social stay hospitalisation/ 社会的入院 HOSPITALIZATION DUE TO SISTER REQUEST	(68) (73) 6 Open-label treatment phase 60 mg/day	MILD/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE INCREASED
	4[redacted]08/ 6[redacted]/ M/ MYS	1	Psychiatric disorders/ 精神障害 Psychotic disorder/ 精神病性障害 Exacerbation of psychotic symptoms with aggression	(23) (40) 18 Double-blind treatment phase 80 mg/day	MILD/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
		501	Psychiatric disorders/ 精神障害 Psychotic disorder/ 精神病性障害 exacerbation of psychotic symptoms	(71) (81) 11 Open-label treatment phase 40 mg/day	MILD/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
		503	General disorders and administration site conditions/ 一般・全身障害および投与部位の状態 Death/死亡 Natural cause of death due to old age	(123) (123) 1 Open-label treatment phase 60 mg/day *	SEVERE/ NOT RELATED/ Y (Results in death)	FATAL/ NOT APPLICABLE
[redacted]	5[redacted]10/ 3[redacted]/ M/ PHL	1	Injury, poisoning and procedural complications/ 傷害、中毒および処置合併症 Traumatic haematoma/ 外傷性血腫 Contusion Hematomas, left zygoma and left supraorbital area	(19) (26) 8 Double-blind treatment phase 80 mg/day	MILD/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
[redacted]	5[redacted]09/ 4[redacted]/ F/ PHL	501	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 relapse of symptoms/Schizophrenia	(119) ONGOING - Open-label treatment phase 40 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
	5[redacted]11/ 3[redacted]/ M/ PHL	2	Infections and infestations/ 感染症および寄生虫症 Pulmonary tuberculosis/ 肺結核 Pulmonary Tuberculosis	(41) ONGOING - Double-blind treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	5[redacted]01/ 2[redacted]/ F/ PHL	506	Psychiatric disorders/ 精神障害 Completed suicide/自殺既遂 Suicide attempt completed	(142) (142) 1 Open-label treatment phase 40 mg/day	SEVERE/ NOT RELATED/ Y (Results in death)	FATAL/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]02/ 4[redacted]/ M/ JPN	1	Psychiatric disorders/ 精神障害 Catatonia/カタトニー Catatonia	(19) ONGOING - Double-blind treatment phase 0 mg/day	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]04/ 7[redacted]/ M/ JPN	503	Psychiatric disorders/精神障害 Schizophrenia/ 統合失調症 Schizophrenia aggravated	(142) (177) 36 Open-label treatment phase 60 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE INCREASED
	1[redacted]06/ 6[redacted]/ F/ JPN	1	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 schizophrenia aggravated	(-23) ONGOING - Double-blind treatment phase 0 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DOSE NOT CHANGED
		501 (1)	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Schizophrenia aggravated	(-23) (16) 39 Double-blind treatment phase 0 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
[redacted]	1[redacted]06/ 4[redacted]/ M/ JPN	505	Investigations/ 臨床検査 Weight increased/ 体重増加 Loss of control of weight(Weight Increased)	(210) (245) 36 Open-label treatment phase 60 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
[redacted]	1[redacted]01/ 2[redacted]/ F/ JPN	507	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsoring of schizophrenia	(89) (103) 15 Open-label treatment phase 80 mg/day *	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]01/ 6[redacted]/ F/ JPN	3	Nervous system disorders/ 神経系障害 Loss of consciousness/ 意識消失 Transient loss of consciousness	(24) (27) 4 Follow-up phase 0 mg/day *	MILD/ POSSIBLE/ Y (Other medically important event)	RECOVERED/RESOLVED/ NOT APPLICABLE
[redacted]	1[redacted]01/ 4[redacted]/ M/ JPN	508	General disorders and administration site conditions/ 一般・全身障害および投与部位の状態 Sudden death/ 突然死 Sudden death	(356) (356) 1 Open-label treatment phase 60 mg/day *	SEVERE/ POSSIBLE/ Y (Results in death)	FATAL/ DRUG WITHDRAWN
[redacted]	2[redacted]03/ 4[redacted]/ F/ KOR	2	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of schizophrenia	(8) ONGOING - Double-blind treatment phase 0 mg/day *	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]05/ 5[redacted]/ M/ KOR	524	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of Schizophrenia	(129) ONGOING - Open-label treatment phase 80 mg/day *	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ NOT APPLICABLE
[redacted]	2[redacted]02/ 5[redacted]/ F/ KOR	513	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of schizophrenia	(58) ONGOING - Open-label treatment phase 80 mg/day	MILD/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DOSE NOT CHANGED
[redacted]	4[redacted]20/ 3[redacted]/ M/ MYS	502	Psychiatric disorders/ 精神障害 Psychotic disorder/ 精神病性障害 worsening psychosis	(87) (98) 12 Open-label treatment phase 80 mg/day	MODERATE/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
	4[redacted]27/ 5[redacted]/ F/ MYS	501	Psychiatric disorders/ 精神障害 Psychotic disorder/ 精神病性障害 worsening of psychosis	(23) (36) 14 Open-label treatment phase 80 mg/day *	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ NOT APPLICABLE
[redacted]	4[redacted]04/ 5[redacted]/ F/ MYS	502	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening Of Schizophrenia	(21) (50) 30 Open-label treatment phase 40 mg/day	SEVERE/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]04/ 3[redacted]/ M/ MYS	508	Injury, poisoning and procedural complications/ 傷害、中毒および処置合併症 Toxicity to various agents/ 各種物質毒性 Methamphetamine Intoxication	(86) ONGOING - Open-label treatment phase 60 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
	4[redacted]11/ 3[redacted]/ F/ MYS	1	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of Schizophrenia	(-16) ONGOING - Double-blind treatment phase 0 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DOSE NOT CHANGED
		501 (1)	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of Schizophrenia	(-16) (12) 28 Double-blind treatment phase 0 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
		502	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of Schizophrenia	(24) ONGOING - Open-label treatment phase 60 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DOSE NOT CHANGED

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	4[redacted]19/ 4[redacted]/ M/ MYS	510	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Relapse Due to Probable non compliance	(89) (95) 7 Open-label treatment phase 80 mg/day	MILD/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
	4[redacted]22/ 3[redacted]/ M/ MYS	505	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Relapse due to poor compliance	(155) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
	4[redacted]29/ 4[redacted]/ M/ MYS	502	Psychiatric disorders/ 精神障害 Suicidal ideation/ 自殺念慮 Suicide Risk due to Psychosis	(15) (16) 2 Open-label treatment phase 80 mg/day	SEVERE/ POSSIBLE/ Y (Life threatening)	RECOVERED/RESOLVED/ DOSE INCREASED
[redacted]	4[redacted]01/ 5[redacted]/ M/ MYS	1	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of Schizophrenia	(-26) ONGOING - Double-blind treatment phase 0 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DOSE NOT CHANGED
		502 (1)	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 Worsening of Schizophrenia	(-26) (48) 74 Double-blind treatment phase 0 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
[redacted]	4[redacted]03/ 3[redacted]/ F/ MYS	511	Psychiatric disorders/ 精神障害 Schizophrenia/ 統合失調症 schizophrenia	(84) (104) 21 Open-label treatment phase 40 mg/day	MILD/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE INCREASED

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	4[redacted]03/ 3[redacted]/ F/ MYS	1	Social circumstances/ 社会環境 Social stay hospitalisation/社会的入院 Hospitalization due to parents request.	(-16) (1) 17 Double-blind treatment phase 0 mg/day	MILD/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
	4[redacted]05/ 3[redacted]/ M/ MYS	9	Psychiatric disorders/精神障害 Psychotic disorder/ 精神病性障害 Exacerbation of psychotic symptoms and aggression	(-16) (-10) 7 Double-blind treatment phase 0 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE NOT CHANGED
		501	Psychiatric disorders/ 精神障害 Psychotic disorder/ 精神病性障害 Exacerbation of psychotic symptoms and very irritability	(11) (21) 11 Open-label treatment phase 60 mg/day	MODERATE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DOSE INCREASED
[redacted]	5[redacted]04/ 3[redacted]/ M/ PHL	3	Psychiatric disorders/ 精神障害 Psychotic disorder/精神病性障害 Worsening of psychotic symptoms related to Schizophrenia	(18) ONGOING - Double-blind treatment phase 0 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	5[redacted]04/ 2[redacted]/ M/ PHL	502	Psychiatric disorders/精神障害 Psychotic disorder/ 精神病性障害 Exacerbation of Psychosis Symptoms	(122) (167) 46 Open-label treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	6[redacted]04/ 6[redacted]/ M/ CHN	501	Gastrointestinal disorders/ 胃腸障害 Upper gastrointestinal haemorrhage/ 上部消化管出血 Upper gastrointestinal bleeding	(9) (25) 17 Open-label treatment phase 60 mg/day *	MODERATE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN

JPN = JAPAN, CHN = CHINA, KOR = KOREA, REPUBLIC OF, MYS = MALAYSIA, PHL = PHILIPPINES, RUS = RUSSIAN FEDERATION, TWN = TAIWAN, UKR = UKRAINE

Adverse events are coded by MedDRA version 19.1. In case that subjects didn't recieve an active treatment, study day (Day) is relative to the initial application in the double-blind treatment phase, but if subjects recieved an active treatment, study day (Day) is relative to the first day of receiving an active treatment regardless of treatment phase.

(#): No. in DB treatment (only in case of the ongoing AE from DB treatment) or No. in the Open-label phase (only in the case of worsened during the Open-label phase)

*, in the case that the dose at onset date is zero or missing, the most recent non-zero dose is displayed.

The final data at Open-Week 52 was used.

Control No:<<l16-03-01-02-ae.sas, 2018-11-14T20:26:31>>

表2.7.4.7-21　治験薬の貼付中止に至った有害事象の一覧（20試験・ロナセンテープ貼付期、Open-52週）
All Patients

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]07/ 3[redacted]/ M/ JPN	501	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 aggravation of schizophrenia	(80) ONGOING - Open-label treatment phase 80 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 5[redacted]/ F/ JPN	3	Nervous system disorders/神経系障害 Generalised tonic-clonic seizure/全身性強直性間代性発作 Tonic-clonic convulsions	(20) (21) 2 Double-blind treatment phase 40 mg/day	SEVERE/ POSSIBLE/ Y (Other medically important event)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 4[redacted]/ F/ JPN	3	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(3) ONGOING - Double-blind treatment phase 40 mg/day *	MODERATE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 7[redacted]/ F/ JPN	1	Nervous system disorders/神経系障害 Dyskinesia/ジスキネジア tongue dyskinesia	(4) ONGOING - Double-blind treatment phase 40 mg/day	MILD/ DEFINITE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
		2	Metabolism and nutrition disorders/代謝および栄養障害 Decreased appetite/食欲減退 anorexia aggravated	(10) ONGOING - Double-blind treatment phase 40 mg/day	MILD/ DEFINITE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
		3	Nervous system disorders/神経系障害 Akinesia/無動 akinesia	(10) ONGOING - Double-blind treatment phase 40 mg/day	MILD/ DEFINITE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
	1[redacted]04/ 2[redacted]/ F/ JPN	506 (1)	Investigations/臨床検査 Weight increased/体重増加 Weight gain	(30) ONGOING - Double-blind treatment phase 40 mg/day	MILD/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 5[redacted]/ F/ JPN	516	Injury, poisoning and procedural complications/傷害、中毒および処置合併症 Femoral neck fracture/大腿骨頚部骨折 right femoral neck fracture	(321) ONGOING - Open-label treatment phase 60 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 6[redacted]/ F/ JPN	1	Psychiatric disorders/精神障害 Suicidal ideation/自殺念慮 suicidal ideation	(6) ONGOING - Double-blind treatment phase 40 mg/day	MODERATE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 4[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Aggravation of schizophrenia	(14) ONGOING - Double-blind treatment phase 40 mg/day *	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 5[redacted]/ M/ JPN	504	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of Schizophrenia	(128) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]03/ 2[redacted]/ F/ JPN	506	Psychiatric disorders/精神障害 Suicidal ideation/自殺念慮 suicidal idea	(179) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]08/ 6[redacted]/ M/ JPN	2	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of shizophrenia	(4) ONGOING - Double-blind treatment phase 40 mg/day	MODERATE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 5[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(9) (14) 6 Double-blind treatment phase 40 mg/day	SEVERE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
		2	Psychiatric disorders/精神障害 Sexually inappropriate behaviour/不適切な性的行動 Sexually inappropriate behaviour	(9) (14) 6 Double-blind treatment phase 40 mg/day	SEVERE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]07/ 3[redacted]/ M/ KOR	6	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of Schizophrenia	(26) (32) 7 Double-blind treatment phase 40 mg/day	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]01/ 3[redacted]/ F/ KOR	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of schizophrenia	(-2) ONGOING - Washout phase 0 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	3[redacted]11/ 3[redacted]/ M/ TWN	505	Psychiatric disorders/精神障害 Suicide attempt/自殺企図 Sucide attempt	(146) ONGOING - Open-label treatment phase 80 mg/day *	MILD/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]02/ 4[redacted]/ M/ MYS	3	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Exacerbation of psychosis	(17) ONGOING - Double-blind treatment phase 40 mg/day	MODERATE/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]03/ 3[redacted]/ F/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 worsening of psychosis	(10) ONGOING - Double-blind treatment phase 40 mg/day	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	4[redacted]08/ 3[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Worsening of psychosis	(12) (20) 9 Double-blind treatment phase 40 mg/day	MODERATE/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]15/ 4[redacted]/ F/ MYS	2	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 worsening of psychotic symptom	(9) (10) 2 Double-blind treatment phase 40 mg/day *	SEVERE/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]24/ 3[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Exacerbation of psychosis	(31) ONGOING - Double-blind treatment phase 40 mg/day	SEVERE/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
	4[redacted]28/ 5[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Worsening of psychosis	(3) (6) 4 Double-blind treatment phase 40 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]37/ 1[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Worsening psychosis	(7) (13) 7 Double-blind treatment phase 40 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]05/ 4[redacted]/ F/ MYS	501	Musculoskeletal and connective tissue disorders/筋骨格系および結合組織障害 Limb discomfort/四肢不快感 FEELING HEAVINESS OF BOTH LEGS	(46) (55) 10 Open-label treatment phase 40 mg/day	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]10/ 2[redacted]/ F/ MYS	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 WORSENING SCHIZOPHRENIA	(21) ONGOING - Double-blind treatment phase 40 mg/day	SEVERE/ PROBABLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]03/ 3[redacted]/ M/ MYS	502	Psychiatric disorders/精神障害 Abnormal behaviour/異常行動 Worsening of Symptoms (Changing of behavior)	(110) (124) 15 Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]05/ 4[redacted]/ F/ MYS	512	Psychiatric disorders/精神障害/ Aggression/攻撃性 Worsening of Symptom of aggressive behavior	(74) (75) 2 Open-label treatment phase 80 mg/day *	MODERATE/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

DSP-5423P 40 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	6[redacted]05/ 5[redacted] F/ CHN	501	Hepatobiliary disorders/肝胆道系障害 Hepatic function abnormal/肝機能異常 Abnormal liver function exacerbation	(134) ONGOING - Open-label treatment phase 40 mg/day	SEVERE/ PROBABLE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	7[redacted]06/ 3[redacted] M/ RUS	512	Psychiatric disorders/精神障害 Psychiatric symptom/精神症状 Worsening of psychic state	(175) (215) 41 Open-label treatment phase 80 mg/day	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	7[redacted]04/ 4[redacted] F/ RUS	502	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of schizophrenia	(53) (63) 11 Open-label treatment phase 60 mg/day	SEVERE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]03/ 3[redacted]/ M/ JPN	502	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(156) ONGOING - Open-label treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 5[redacted]/ F/ JPN	511	Psychiatric disorders/精神障害 Hallucination/幻覚 worsening of Hallucination	(270) ONGOING - Open-label treatment phase 80 mg/day *	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 4[redacted]/ F/ JPN	512	Psychiatric disorders/精神障害 Psychiatric symptom/精神症状 Worsening of psychiatric symptom	(356) ONGOING - Open-label treatment phase 40 mg/day *	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 5[redacted]/ F/ JPN	3	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site pruritus/適用部位そう痒感 itching(application site)	(-5) (24) 29 Washout phase 0 mg/day	MILD/ DEFINITE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 7[redacted]/ F/ JPN	501 (1)	Nervous system disorders/神経系障害 Akathisia/アカシジア akathisia	(8) ONGOING - Double-blind treatment phase 80 mg/day	SEVERE/ DEFINITE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
		502 (2)	Nervous system disorders/神経系障害/ Parkinsonian gait/パーキンソン歩行 short-stepped gait	(16) ONGOING - Double-blind treatment phase 80 mg/day	MODERATE/ DEFINITE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
		503 (3)	Musculoskeletal and connective tissue disorders/筋骨格系および結合組織障害/ Muscle rigidity/筋固縮 muscle rigidity	(16) (72) 57 Double-blind treatment phase 80 mg/day	MODERATE/ DEFINITE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]04/ 2[redacted]/ F/ JPN	501	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of Schizophrenia	(74) (92) 19 Open-label treatment phase 60 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 5[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(11) ONGOING - Double-blind treatment phase 80 mg/day	SEVERE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
	1[redacted]04/ 7[redacted]/ M/ JPN	503	Gastrointestinal disorders/胃腸障害 Nausea/悪心 Queasy	(58) (73) 16 Open-label treatment phase 40 mg/day	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]04/ 2[redacted]/ F/ JPN	505	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggrevated	(47) ONGOING - Open-label treatment phase 40 mg/day *	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	1[redacted]06/ 5[redacted]/ F/ JPN	503	Infections and infestations/感染症および寄生虫症 Intervertebral discitis/椎間板炎 Purulent diskitis	(292) (554) 263 Open-label treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	2[redacted]04/ 2[redacted]/ M/ KOR	1	Psychiatric disorders/精神障害 Agitation/激越 psychotic agitation	(25) ONGOING - Double-blind treatment phase 80 mg/day	MILD/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]01/ 3[redacted]/ M/ KOR	2	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of schizophrenia	(7) (40) 34 Double-blind treatment phase 80 mg/day	SEVERE/ DEFINITE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]08/ 2[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Suicide attempt/自殺企図 Suicidal attempt	(22) (31) 10 Double-blind treatment phase 80 mg/day *	SEVERE/ PROBABLE/ Y (Life threatening, Requires or prolongs hospitalization)	RECOVERED/RESOLVED WITH SEQUELAE/ DRUG WITHDRAWN
		2	Injury, poisoning and procedural complications/傷害、中毒および処置合併症 Pulmonary contusion/肺挫傷 BILATERAL LUNGS CONTUSSION	(22) (31) 10 Double-blind treatment phase 80 mg/day *	SEVERE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
		3	Injury, poisoning and procedural complications/傷害、中毒および処置合併症 Ankle fracture/足関節部骨折 LEFT CALCANEUM FRACTURE	(22) ONGOING - Double-blind treatment phase 80 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
		4	Injury, poisoning and procedural complications/傷害、中毒および処置合併症 Clavicle fracture/鎖骨骨折 RIGHT CLAVICLE FRACTURE	(22) ONGOING - Double-blind treatment phase 80 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
		5	Respiratory, thoracic and mediastinal disorders/呼吸器、胸郭および縦隔障害 Pulmonary embolism/肺塞栓症 TRO PULMONARY EMBOLISM	(26) (30) 5 Follow-up phase 80 mg/day *	SEVERE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]06/ 3[redacted]/ M/ MYS	1	Investigations/臨床検査 Blood creatine phosphokinase increased/血中クレアチンホスホキナーゼ増加 WORSENING OF CK ELEVATION	(4) (15) 12 Double-blind treatment phase 80 mg/day	MODERATE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]16/ 2[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 WORSENING OF PSYCHOTIC SYMPTOMS	(11) (19) 9 Double-blind treatment phase 80 mg/day	MODERATE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]12/ 6[redacted]/ M/ MYS	1	Infections and infestations/感染症および寄生虫症 Pneumonia/肺炎 Pneumonia	(5) (12) 8 Double-blind treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Other medically important event)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]18/ 4[redacted]/ M/ MYS	1	Cardiac disorders/心臓障害 Acute myocardial infarction/急性心筋梗塞 Cardiogenic shock secondary to NSTEMI	(35) (36) 2 Double-blind treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Results in death, Requires or prolongs hospitalization)	FATAL/ DRUG WITHDRAWN
	4[redacted]25/ 4[redacted]/ M/ MYS	501	Gastrointestinal disorders/胃腸障害 Colitis/大腸炎 Colitis	(71) (71) 1 Open-label treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Results in death)	FATAL/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
	4[redacted]29/ 2[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 worsening of psychosis	(8) (16) 9 Double-blind treatment phase 80 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]01/ 3[redacted]/ F/ MYS	502	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of Schizophrenia	(99) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
	4[redacted]08/ 3[redacted]/ M/ MYS	1	Nervous system disorders/神経系障害 Guillain-Barre syndrome/ギラン・バレー症候群 GUILLAIN BARRE SYNDROME	(3) ONGOING - Double-blind treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Results in persistent or significant disability/incapacity)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]04/ 2[redacted]/ M/ MYS	502	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of schizophrenia symptoms	(134) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ PROBABLE/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	5[redacted]09/ 4[redacted]/ F/. PHL	501	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 relapse of symptoms/Schizophrenia	(119) ONGOING - Open-label treatment phase 40 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
	5[redacted]11/ 3[redacted]/ M/ PHL	2	Infections and infestations/感染症および寄生虫症 Pulmonary tuberculosis/肺結核 Pulmonary Tuberculosis	(41) ONGOING - Double-blind treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN

DSP-5423P 80 mg

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	5[redacted]01/ 2[redacted]/ F/ PHL	506	Psychiatric disorders/精神障害 Completed suicide/自殺既遂 Suicide attempt completed	(142) (142) 1 Open-label treatment phase 40 mg/day	SEVERE/ NOT RELATED/ Y (Results in death)	FATAL/ DRUG WITHDRAWN
[redacted]	7[redacted]02/ 5[redacted]/ F/ RUS	501	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of schizophrenia	(60) ONGOING - Open-label treatment phase 80 mg/day *	SEVERE/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	8[redacted]05/ 2[redacted]/ M/ UKR	501	Psychiatric disorders/精神障害 Psychiatric symptom/精神症状 worsening of psychiatric symptoms	(155) (161) 7 Open-label treatment phase 80 mg/day	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]02/ 4[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Catatonia/カタトニー Catatonia	(19) ONGOING - Double-blind treatment phase 0 mg/day	SEVERE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 6[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(41) ONGOING - Double-blind treatment phase 0 mg/day	MODERATE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]01/ 2[redacted]/ F/ JPN	507	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsoring of schizophrenia	(89) (103) 15 Open-label treatment phase 80 mg/day *	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 7[redacted]/ F/ JPN	1	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Application site eczema/適用部位湿疹 eczema(application site)	(8) (21) 14 Double-blind treatment phase 0 mg/day	MILD/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 3[redacted]/ F/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 exacerbation of schizophrenic symptoms	(6) ONGOING - Double-blind treatment phase 0 mg/day *	MODERATE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 3[redacted]/ F/ JPN	2	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(10) ONGOING - Double-blind treatment phase 0 mg/day *	SEVERE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]01/ 4[redacted]/ M/ JPN	508	General disorders and administration site conditions/一般・全身障害および投与部位の状態 Sudden death/突然死 Sudden death	(356) (356) 1 Open-label treatment phase 60 mg/day *	SEVERE/ POSSIBLE/ Y (Results in death)	FATAL/ DRUG WITHDRAWN
[redacted]	1[redacted]06/ 5[redacted]/ M/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of Schizophrenia	(9) ONGOING - Double-blind treatment phase 0 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	1[redacted]02/ 5[redacted]/ F/ JPN	5	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Schizophrenia aggravated	(32) ONGOING - Double-blind treatment phase 0 mg/day	SEVERE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
	1[redacted]05/ 6[redacted]/ M/ JPN	516	Psychiatric disorders/精神障害 Insomnia/不眠症 Insomnia	(248) ONGOING - Open-label treatment phase 60 mg/day	MODERATE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]03/ 3[redacted]/ M/ JPN	3	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of schizophrenia	(20) ONGOING - Double-blind treatment phase 0 mg/day	MILD/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	1[redacted]09/ 2[redacted]/ F/ JPN	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of shizophrenia	(5) ONGOING - Double-blind treatment phase 0 mg/day *	MODERATE/ NOT RELATED/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	1[redacted]01/ 6[redacted]/ F/ JPN	4	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 aggravation of Schizophrenia	(30) (32) 3 Double-blind treatment phase 0 mg/day	MODERATE/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]10/ 2[redacted]/ F/ KOR	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of schizophrenia	(1) ONGOING - Double-blind treatment phase 0 mg/day	SEVERE/ NOT RELATED/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	2[redacted]03/ 4[redacted]/ F/ KOR	2	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening of schizophrenia	(8) ONGOING - Double-blind treatment phase 0 mg/day *	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]09/ 3[redacted]/ F/ MYS	506	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 WORSENING OF PSYCHOTIC SYMPTOMS	(161) (175) 15 Open-label treatment phase 60 mg/day	MILD/ NOT RELATED/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]11/ 3[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 worsening of psychosis	(10) (18) 9 Double-blind treatment phase 0 mg/day	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]17/ 5[redacted]/ F/ MYS	501	Cardiac disorders/心臓障害 Bradycardia/徐脈 Bradycardiac	(29) (71) 43 Open-label treatment phase 80 mg/day	MILD/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
	4[redacted]20/ 3[redacted]/ M/ MYS	502	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 worsening psychosis	(87) (98) 12 Open-label treatment phase 80 mg/day	MODERATE/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]36/ 4[redacted]/ F/ MYS	1	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 worsening psychosis	(1) ONGOING - Double-blind treatment phase 0 mg/day	MODERATE/ POSSIBLE/ N	NOT RECOVERED/NOT RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]04/ 5[redacted]/ F/ MYS	502	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Worsening Of Schizophrenia	(21) (50) 30 Open-label treatment phase 40 mg/day	SEVERE/ PROBABLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
	4[redacted]07/ 3[redacted]/ M/ MYS	1	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 worsening of schizophrenia	(10) (35) 26 Double-blind treatment phase 0 mg/day	SEVERE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	4[redacted]04/ 3[redacted]/ M/ MYS	508	Injury, poisoning and procedural complications/傷害、中毒および処置合併症 Toxicity to various agents/各種物質毒性 Methamphetamine Intoxication	(86) ONGOING - Open-label treatment phase 60 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization, Other medically important event)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	4[redacted]22/ 3[redacted]/ M/ MYS	505	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 Relapse due to poor compliance	(155) ONGOING - Open-label treatment phase 80 mg/day	MODERATE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
[redacted]	4[redacted]01/ 6[redacted]/ M/ MYS	501	Psychiatric disorders/精神障害 Schizophrenia/統合失調症 WORSENING OF CLINICAL SYMPTOM SCHIZOPHRENIA (PANSS SCORE FROM 93 TO 110)	(8) ONGOING - Open-label treatment phase 60 mg/day	MODERATE/ PROBABLE/ N	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	5[redacted]04/ 3[redacted]/ M/ PHL	3	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Worsening of psychotic symptoms related to Schizophrenia	(18) ONGOING - Double-blind treatment phase 0 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	5[redacted]04/ 2[redacted]/ M/ PHL	502	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Exacerbation of Psychosis Symptoms	(122) (167) 46 Open-label treatment phase 80 mg/day	SEVERE/ NOT RELATED/ Y (Requires or prolongs hospitalization)	RECOVERING/RESOLVING/ DRUG WITHDRAWN
[redacted]	6[redacted]04/ 6[redacted]/ M/ CHN	501	Gastrointestinal disorders/胃腸障害 Upper gastrointestinal haemorrhage/上部消化管出血 Upper gastrointestinal bleeding	(9) (25) 17 Open-label treatment phase 60 mg/day *	MODERATE/ POSSIBLE/ Y (Requires or prolongs hospitalization)	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	7[redacted]02/ 3[redacted]/ F/ RUS	2	Nervous system disorders/神経系障害 Psychomotor hyperactivity/精神運動亢進 Psychomotor agitation	(7) (22) 16 Double-blind treatment phase 0 mg/day	SEVERE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
		3	Psychiatric disorders/精神障害 Negativism/拒絶症 Negativism	(7) (22) 16 Double-blind treatment phase 0 mg/day	SEVERE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

Placebo

Site	Subject ID/ Age/ Sex/ Country	# (#)	MedDRA System Organ Class/ MedDRA Preferred Term/ Reported Term for the Adverse Event	Start Date (Day) End Date (Day) Duration (days) Epoch of Onset Dose at Onset Date	Severity/ Causality/ Serious Event (Details)	Outcome/ Action Taken with Study Treatment
	7[redacted]04/ 3[redacted]/ F/ RUS	503	Psychiatric disorders/精神障害 Psychiatric symptom/精神症状 Worsening of psychic state	(29) (42) 14 Open-label treatment phase 80 mg/day *	SEVERE/ PROBABLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN
[redacted]	8[redacted]01/ 3[redacted]/ M/ UKR	501	Psychiatric disorders/精神障害 Psychotic disorder/精神病性障害 Exacerbation of psychosis	(8) (15) 8 Open-label treatment phase 40 mg/day *	MODERATE/ POSSIBLE/ N	RECOVERED/RESOLVED/ DRUG WITHDRAWN

JPN = JAPAN, CHN = CHINA, KOR = KOREA, REPUBLIC OF, MYS = MALAYSIA, PHL = PHILIPPINES, RUS = RUSSIAN FEDERATION, TWN = TAIWAN, UKR = UKRAINE

Adverse events are coded by MedDRA version 19.1. In case that subjects didn't recieve an active treatment, study day (Day) is relative to the initial application in the double-blind treatment phase, but if subjects recieved an active treatment, study day (Day) is relative to the first day of receiving an active treatment regardless of treatment phase.

(#): No. in DB treatment (only in case of the ongoing AE from DB treatment) or No. in the Open-label phase (only in the case of worsened during the Open-label phase)

*, in the case that the dose at onset date is zero or missing, the most recent non-zero dose is displayed.

The final data at Open-Week 52 was used.

Control No:<<l16-03-01-03-ae.sas, 2018-11-14T20:26:35>>

表2.7.4.7-22　日本人集団での人口統計学的特性及びその他の特性（20試験・ロナセンテープ貼付期、Open-52週）
DSP-5423P Dosed Population

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
Sex, n (%)					
n	27	55	57	112	139
Male	16 (59.3)	26 (47.3)	29 (50.9)	55 (49.1)	71 (51.1)
Female	11 (40.7)	29 (52.7)	28 (49.1)	57 (50.9)	68 (48.9)
Age (years)					
n	27	55	57	112	139
Mean (SD)	51.6 (14.90)	47.5 (16.03)	48.0 (17.18)	47.8 (16.55)	48.5 (16.26)
Median	53.0	49.0	52.0	49.5	50.0
Min, Max	20, 73	20, 79	22, 81	20, 81	20, 81
Age (years), n (%)					
n	27	55	57	112	139
<65	20 (74.1)	45 (81.8)	46 (80.7)	91 (81.3)	111 (79.9)
>=65	7 (25.9)	10 (18.2)	11 (19.3)	21 (18.8)	28 (20.1)
Race, n (%)					
n	27	55	57	112	139
Asian	27 (100.0)	55 (100.0)	57 (100.0)	112 (100.0)	139 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	27	55	57	112	139
Not Hispanic or Latino	27 (100.0)	55 (100.0)	57 (100.0)	112 (100.0)	139 (100.0)
Country, n (%)					
n	27	55	57	112	139

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
Japan	27 (100.0)	55 (100.0)	57 (100.0)	112 (100.0)	139 (100.0)
China	0	0	0	0	0
Korea	0	0	0	0	0
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	27	55	57	112	139
Mean (SD)	164.08 (10.428)	161.02 (9.431)	160.78 (10.830)	160.90 (10.122)	161.52 (10.222)
Median	163.80	162.10	160.00	160.55	161.50
Min, Max	143.6, 182.0	138.0, 184.2	130.5, 182.0	130.5, 184.2	130.5, 184.2
Weight (kg)					
n	27	55	57	112	139
Mean (SD)	62.63 (15.590)	58.45 (12.770)	56.54 (13.849)	57.48 (13.305)	58.48 (13.870)
Median	61.10	56.20	54.20	56.10	57.00
Min, Max	39.6, 109.9	35.8, 87.9	31.2, 93.6	31.2, 93.6	31.2, 109.9
BMI (kg/m^2)					
n	27	55	57	112	139
Mean (SD)	23.19 (4.895)	22.51 (4.439)	21.67 (3.924)	22.08 (4.187)	22.30 (4.337)
Median	22.32	21.69	20.47	20.92	21.21
Min, Max	17.1, 33.9	15.5, 36.1	13.9, 31.1	13.9, 36.1	13.9, 36.1
Any concomitant diseases, n (%)					
n	27	55	57	112	139
Yes	24 (88.9)	47 (85.5)	52 (91.2)	99 (88.4)	123 (88.5)

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
No	3 (11.1)	8 (14.5)	5 (8.8)	13 (11.6)	16 (11.5)
Hospitalization status at informed consent, n (%)					
n	27	55	57	112	139
Inpatient	23 (85.2)	48 (87.3)	55 (96.5)	103 (92.0)	126 (90.6)
Within 3 months (90 days)	19 (70.4)	33 (60.0)	43 (75.4)	76 (67.9)	95 (68.3)
Over 3 months	4 (14.8)	15 (27.3)	12 (21.1)	27 (24.1)	31 (22.3)
Unknown	0	0	0	0	0
Outpatient	4 (14.8)	7 (12.7)	2 (3.5)	9 (8.0)	13 (9.4)

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Sex, n (%)					
n	8	9	10	19	27
Male	7 (87.5)	1 (11.1)	2 (20.0)	3 (15.8)	10 (37.0)
Female	1 (12.5)	8 (88.9)	8 (80.0)	16 (84.2)	17 (63.0)
Age (years)					
n	8	9	10	19	27
Mean (SD)	47.6 (17.61)	41.8 (15.21)	36.2 (13.73)	38.8 (14.33)	41.4 (15.57)
Median	51.0	39.0	32.0	36.0	39.0
Min, Max	22, 68	24, 62	20, 60	20, 62	20, 68
Age (years), n (%)					
n	8	9	10	19	27
<65	7 (87.5)	9 (100.0)	10 (100.0)	19 (100.0)	26 (96.3)
>=65	1 (12.5)	0	0	0	1 (3.7)
Race, n (%)					
n	8	9	10	19	27
Asian	8 (100.0)	9 (100.0)	10 (100.0)	19 (100.0)	27 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	8	9	10	19	27
Not Hispanic or Latino	8 (100.0)	9 (100.0)	10 (100.0)	19 (100.0)	27 (100.0)
Country, n (%)					
n	8	9	10	19	27
Japan	0	0	0	0	0
China	8 (100.0)	9 (100.0)	10 (100.0)	19 (100.0)	27 (100.0)
Korea	0	0	0	0	0

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	8	9	10	19	27
Mean (SD)	167.19 (6.708)	161.39 (2.759)	164.15 (8.199)	162.84 (6.245)	164.13 (6.573)
Median	166.50	160.00	162.25	160.50	163.50
Min, Max	155.0, 177.0	158.5, 166.0	154.0, 182.0	154.0, 182.0	154.0, 182.0
Weight (kg)					
n	8	9	10	19	27
Mean (SD)	68.93 (17.824)	64.67 (14.499)	67.39 (18.517)	66.10 (16.335)	66.94 (16.492)
Median	61.85	60.00	64.50	60.00	61.00
Min, Max	48.5, 103.0	50.0, 91.5	44.5, 96.5	44.5, 96.5	44.5, 103.0
BMI (kg/m^2)					
n	8	9	10	19	27
Mean (SD)	24.56 (5.483)	24.84 (5.645)	25.02 (6.721)	24.94 (6.063)	24.82 (5.794)
Median	22.85	23.44	23.72	23.44	22.88
Min, Max	17.2, 32.9	18.1, 36.2	17.8, 35.3	17.8, 36.2	17.2, 36.2
Any concomitant diseases, n (%)					
n	8	9	10	19	27
Yes	6 (75.0)	7 (77.8)	5 (50.0)	12 (63.2)	18 (66.7)
No	2 (25.0)	2 (22.2)	5 (50.0)	7 (36.8)	9 (33.3)
Hospitalization status at informed consent, n (%)					

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
n	8	9	10	19	27
Inpatient	8 (100.0)	9 (100.0)	10 (100.0)	19 (100.0)	27 (100.0)
Within 3 months (90 days)	6 (75.0)	7 (77.8)	8 (80.0)	15 (78.9)	21 (77.8)
Over 3 months	2 (25.0)	2 (22.2)	2 (20.0)	4 (21.1)	6 (22.2)
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Sex, n (%)					
n	3	7	7	14	17
Male	1 (33.3)	4 (57.1)	4 (57.1)	8 (57.1)	9 (52.9)
Female	2 (66.7)	3 (42.9)	3 (42.9)	6 (42.9)	8 (47.1)
Age (years)					
n	3	7	7	14	17
Mean (SD)	51.3 (2.08)	39.7 (11.80)	40.4 (10.63)	40.1 (10.80)	42.1 (10.71)
Median	52.0	36.0	43.0	36.5	43.0
Min, Max	49, 53	27, 64	23, 56	23, 64	23, 64
Age (years), n (%)					
n	3	7	7	14	17
<65	3 (100.0)	7 (100.0)	7 (100.0)	14 (100.0)	17 (100.0)
>=65	0	0	0	0	0
Race, n (%)					
n	3	7	7	14	17
Asian	3 (100.0)	7 (100.0)	7 (100.0)	14 (100.0)	17 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	3	7	7	14	17
Not Hispanic or Latino	3 (100.0)	7 (100.0)	7 (100.0)	14 (100.0)	17 (100.0)
Country, n (%)					
n	3	7	7	14	17
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	3 (100.0)	7 (100.0)	7 (100.0)	14 (100.0)	17 (100.0)

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	3	7	7	14	17
Mean (SD)	155.30 (7.973)	163.51 (10.425)	168.50 (10.162)	166.01 (10.223)	164.12 (10.515)
Median	156.00	158.50	169.60	166.55	162.90
Min, Max	147.0, 162.9	152.0, 181.5	154.9, 180.5	152.0, 181.5	147.0, 181.5
Weight (kg)					
n	3	7	7	14	17
Mean (SD)	53.97 (7.900)	59.83 (21.166)	64.71 (8.051)	62.27 (15.592)	60.81 (14.696)
Median	52.20	48.20	66.80	61.65	61.60
Min, Max	47.1, 62.6	41.8, 96.8	51.1, 73.9	41.8, 96.8	41.8, 96.8
BMI (kg/m^2)					
n	3	7	7	14	17
Mean (SD)	22.37 (2.625)	21.83 (4.892)	22.78 (2.062)	22.31 (3.640)	22.32 (3.410)
Median	23.59	20.43	22.01	21.54	21.54
Min, Max	19.4, 24.2	16.6, 29.4	20.7, 25.7	16.6, 29.4	16.6, 29.4
Any concomitant diseases, n (%)					
n	3	7	7	14	17
Yes	3 (100.0)	6 (85.7)	5 (71.4)	11 (78.6)	14 (82.4)
No	0	1 (14.3)	2 (28.6)	3 (21.4)	3 (17.6)
Hospitalization status at informed consent, n (%)					

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
n	3	7	7	14	17
Inpatient	3 (100.0)	7 (100.0)	6 (85.7)	13 (92.9)	16 (94.1)
Within 3 months (90 days)	2 (66.7)	7 (100.0)	5 (71.4)	12 (85.7)	14 (82.4)
Over 3 months	0	0	1 (14.3)	1 (7.1)	1 (5.9)
Unknown	1 (33.3)	0	0	0	1 (5.9)
Outpatient	0	0	1 (14.3)	1 (7.1)	1 (5.9)

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Sex, n (%)					
n	43	58	54	112	155
Male	29 (67.4)	41 (70.7)	41 (75.9)	82 (73.2)	111 (71.6)
Female	14 (32.6)	17 (29.3)	13 (24.1)	30 (26.8)	44 (28.4)
Age (years)					
n	43	58	54	112	155
Mean (SD)	40.4 (9.92)	36.9 (10.57)	35.9 (11.95)	36.4 (11.22)	37.5 (10.99)
Median	38.0	38.0	35.0	35.5	37.0
Min, Max	22, 62	19, 62	18, 69	18, 69	18, 69
Age (years), n (%)					
n	43	58	54	112	155
<65	43 (100.0)	58 (100.0)	53 (98.1)	111 (99.1)	154 (99.4)
>=65	0	0	1 (1.9)	1 (0.9)	1 (0.6)
Race, n (%)					
n	43	58	54	112	155
Asian	43 (100.0)	58 (100.0)	54 (100.0)	112 (100.0)	155 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	43	58	54	112	155
Not Hispanic or Latino	43 (100.0)	58 (100.0)	54 (100.0)	112 (100.0)	155 (100.0)
Country, n (%)					
n	43	58	54	112	155
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Malaysia	43 (100.0)	58 (100.0)	54 (100.0)	112 (100.0)	155 (100.0)
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	43	58	54	112	155
Mean (SD)	163.78 (9.293)	163.27 (9.886)	163.85 (9.204)	163.55 (9.525)	163.61 (9.432)
Median	164.00	164.00	165.25	164.75	164.30
Min, Max	148.0, 186.0	125.0, 185.0	136.0, 180.0	125.0, 185.0	125.0, 186.0
Weight (kg)					
n	43	58	54	112	155
Mean (SD)	64.63 (13.887)	63.81 (15.358)	63.98 (14.815)	63.89 (15.031)	64.10 (14.682)
Median	63.00	60.00	61.25	60.45	61.00
Min, Max	44.9, 122.0	41.0, 118.0	27.9, 103.0	27.9, 118.0	27.9, 122.0
BMI (kg/m^2)					
n	43	58	54	112	155
Mean (SD)	24.19 (5.236)	24.10 (6.230)	23.83 (5.179)	23.97 (5.724)	24.03 (5.577)
Median	23.18	23.23	23.18	23.22	23.19
Min, Max	16.9, 43.7	14.5, 46.8	13.6, 35.6	13.6, 46.8	13.6, 46.8
Any concomitant diseases, n (%)					
n	43	58	54	112	155
Yes	16 (37.2)	25 (43.1)	22 (40.7)	47 (42.0)	63 (40.6)
No	27 (62.8)	33 (56.9)	32 (59.3)	65 (58.0)	92 (59.4)
Hospitalization status at informed consent, n (%)					

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
n	43	58	54	112	155
Inpatient	43 (100.0)	58 (100.0)	54 (100.0)	112 (100.0)	155 (100.0)
Within 3 months (90 days)	42 (97.7)	56 (96.6)	54 (100.0)	110 (98.2)	152 (98.1)
Over 3 months	1 (2.3)	2 (3.4)	0	2 (1.8)	3 (1.9)
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Sex, n (%)					
n	22	22	22	44	66
Male	15 (68.2)	19 (86.4)	16 (72.7)	35 (79.5)	50 (75.8)
Female	7 (31.8)	3 (13.6)	6 (27.3)	9 (20.5)	16 (24.2)
Age (years)					
n	22	22	22	44	66
Mean (SD)	33.6 (9.94)	32.7 (9.24)	32.4 (9.07)	32.5 (9.05)	32.9 (9.29)
Median	33.0	33.0	31.0	32.5	32.5
Min, Max	19, 56	20, 57	20, 55	20, 57	19, 57
Age (years), n (%)					
n	22	22	22	44	66
<65	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
>=65	0	0	0	0	0
Race, n (%)					
n	22	22	22	44	66
Asian	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	22	22	22	44	66
Not Hispanic or Latino	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
Country, n (%)					
n	22	22	22	44	66
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Malaysia	0	0	0	0	0
Philippines	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	22	22	22	44	66
Mean (SD)	158.75 (8.570)	161.68 (6.170)	161.85 (7.570)	161.77 (6.825)	160.76 (7.523)
Median	158.50	161.80	164.75	162.80	161.00
Min, Max	137.0, 172.7	147.3, 175.0	145.0, 172.0	145.0, 175.0	137.0, 175.0
Weight (kg)					
n	22	22	22	44	66
Mean (SD)	58.92 (10.267)	58.77 (9.044)	59.60 (7.628)	59.18 (8.279)	59.10 (8.911)
Median	56.45	56.95	58.45	58.20	57.35
Min, Max	47.5, 90.2	42.8, 79.0	48.0, 74.7	42.8, 79.0	42.8, 90.2
BMI (kg/m^2)					
n	22	22	22	44	66
Mean (SD)	23.43 (4.038)	22.46 (2.984)	22.76 (2.556)	22.61 (2.750)	22.89 (3.228)
Median	22.56	22.22	22.89	22.43	22.51
Min, Max	19.1, 37.1	15.7, 27.9	18.8, 26.9	15.7, 27.9	15.7, 37.1
Any concomitant diseases, n (%)					
n	22	22	22	44	66
Yes	3 (13.6)	2 (9.1)	4 (18.2)	6 (13.6)	9 (13.6)
No	19 (86.4)	20 (90.9)	18 (81.8)	38 (86.4)	57 (86.4)
Hospitalization status at informed consent, n (%)					

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
n	22	22	22	44	66
Inpatient	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
Within 3 months (90 days)	21 (95.5)	21 (95.5)	22 (100.0)	43 (97.7)	64 (97.0)
Over 3 months	1 (4.5)	1 (4.5)	0	1 (2.3)	2 (3.0)
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Sex, n (%)					
n	10	13	12	25	35
Male	5 (50.0)	6 (46.2)	5 (41.7)	11 (44.0)	16 (45.7)
Female	5 (50.0)	7 (53.8)	7 (58.3)	14 (56.0)	19 (54.3)
Age (years)					
n	10	13	12	25	35
Mean (SD)	33.7 (12.12)	39.5 (15.20)	42.8 (10.66)	41.0 (13.05)	38.9 (13.06)
Median	32.0	37.0	44.0	40.0	37.0
Min, Max	18, 54	18, 68	23, 59	18, 68	18, 68
Age (years), n (%)					
n	10	13	12	25	35
<65	10 (100.0)	12 (92.3)	12 (100.0)	24 (96.0)	34 (97.1)
>=65	0	1 (7.7)	0	1 (4.0)	1 (2.9)
Race, n (%)					
n	10	13	12	25	35
Asian	0	1 (7.7)	0	1 (4.0)	1 (2.9)
White	10 (100.0)	12 (92.3)	12 (100.0)	24 (96.0)	34 (97.1)
Ethnicity, n (%)					
n	10	13	12	25	35
Not Hispanic or Latino	10 (100.0)	13 (100.0)	12 (100.0)	25 (100.0)	35 (100.0)
Country, n (%)					
n	10	13	12	25	35
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	10 (100.0)	13 (100.0)	12 (100.0)	25 (100.0)	35 (100.0)
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	10	13	12	25	35
Mean (SD)	173.80 (13.054)	166.12 (11.832)	165.17 (8.288)	165.66 (10.086)	167.99 (11.438)
Median	173.50	166.00	166.50	166.00	168.00
Min, Max	150.0, 200.0	140.0, 181.0	145.0, 174.0	140.0, 181.0	140.0, 200.0
Weight (kg)					
n	10	13	12	25	35
Mean (SD)	88.01 (31.086)	66.85 (14.129)	70.41 (17.985)	68.56 (15.854)	74.11 (22.644)
Median	77.70	65.70	67.65	65.70	69.70
Min, Max	53.0, 149.8	48.1, 86.1	50.2, 118.7	48.1, 118.7	48.1, 149.8
BMI (kg/m^2)					
n	10	13	12	25	35
Mean (SD)	29.02 (9.266)	24.27 (4.647)	26.03 (7.402)	25.11 (6.059)	26.23 (7.201)
Median	26.39	26.01	24.20	24.44	24.44
Min, Max	19.7, 44.2	16.6, 31.5	16.8, 45.8	16.6, 45.8	16.6, 45.8
Any concomitant diseases, n (%)					
n	10	13	12	25	35
Yes	7 (70.0)	8 (61.5)	9 (75.0)	17 (68.0)	24 (68.6)
No	3 (30.0)	5 (38.5)	3 (25.0)	8 (32.0)	11 (31.4)
Hospitalization status at informed consent, n (%)					

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
n	10	13	12	25	35
Inpatient	10 (100.0)	13 (100.0)	12 (100.0)	25 (100.0)	35 (100.0)
Within 3 months (90 days)	10 (100.0)	13 (100.0)	12 (100.0)	25 (100.0)	35 (100.0)
Over 3 months	0	0	0	0	0
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Sex, n (%)					
n	5	15	17	32	37
Male	3 (60.0)	8 (53.3)	8 (47.1)	16 (50.0)	19 (51.4)
Female	2 (40.0)	7 (46.7)	9 (52.9)	16 (50.0)	18 (48.6)
Age (years)					
n	5	15	17	32	37
Mean (SD)	42.0 (13.29)	39.1 (7.17)	43.4 (9.97)	41.4 (8.89)	41.5 (9.37)
Median	42.0	39.0	43.0	40.5	41.0
Min, Max	23, 58	25, 49	24, 61	24, 61	23, 61
Age (years), n (%)					
n	5	15	17	32	37
<65	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
>=65	0	0	0	0	0
Race, n (%)					
n	5	15	17	32	37
Asian	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	5	15	17	32	37
Not Hispanic or Latino	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
Country, n (%)					
n	5	15	17	32	37
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
Ukraine	0	0	0	0	0
Height (cm)					
n	5	15	17	32	37
Mean (SD)	159.70 (8.628)	165.29 (8.637)	162.95 (9.465)	164.04 (9.019)	163.46 (8.976)
Median	157.00	167.00	162.00	163.85	163.00
Min, Max	151.0, 173.0	148.0, 178.0	149.0, 180.0	148.0, 180.0	148.0, 180.0
Weight (kg)					
n	5	15	17	32	37
Mean (SD)	62.90 (15.892)	66.83 (15.405)	65.38 (14.400)	66.06 (14.654)	65.64 (14.635)
Median	70.00	67.00	67.50	67.25	67.50
Min, Max	42.0, 76.5	46.0, 92.0	43.2, 92.0	43.2, 92.0	42.0, 92.0
BMI (kg/m^2)					
n	5	15	17	32	37
Mean (SD)	24.42 (4.675)	24.18 (3.617)	24.60 (5.116)	24.40 (4.412)	24.41 (4.380)
Median	25.56	24.05	23.49	23.77	24.05
Min, Max	17.6, 28.6	18.9, 31.4	18.4, 37.3	18.4, 37.3	17.6, 37.3
Any concomitant diseases, n (%)					
n	5	15	17	32	37
Yes	3 (60.0)	13 (86.7)	12 (70.6)	25 (78.1)	28 (75.7)
No	2 (40.0)	2 (13.3)	5 (29.4)	7 (21.9)	9 (24.3)
Hospitalization status at informed consent, n (%)					

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
n	5	15	17	32	37
Inpatient	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
Within 3 months (90 days)	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
Over 3 months	0	0	0	0	0
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Sex, n (%)					
n	13	17	15	32	45
Male	9 (69.2)	11 (64.7)	10 (66.7)	21 (65.6)	30 (66.7)
Female	4 (30.8)	6 (35.3)	5 (33.3)	11 (34.4)	15 (33.3)
Age (years)					
n	13	17	15	32	45
Mean (SD)	39.2 (7.69)	44.7 (9.14)	39.3 (12.60)	42.2 (11.07)	41.3 (10.21)
Median	37.0	45.0	37.0	43.0	42.0
Min, Max	26, 49	26, 60	20, 64	20, 64	20, 64
Age (years), n (%)					
n	13	17	15	32	45
<65	13 (100.0)	17 (100.0)	15 (100.0)	32 (100.0)	45 (100.0)
>=65	0	0	0	0	0
Race, n (%)					
n	13	17	15	32	45
Asian	0	0	0	0	0
White	13 (100.0)	17 (100.0)	15 (100.0)	32 (100.0)	45 (100.0)
Ethnicity, n (%)					
n	13	17	15	32	45
Not Hispanic or Latino	13 (100.0)	17 (100.0)	15 (100.0)	32 (100.0)	45 (100.0)
Country, n (%)					
n	13	17	15	32	45
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	13 (100.0)	17 (100.0)	15 (100.0)	32 (100.0)	45 (100.0)
Height (cm)					
n	13	17	15	32	45
Mean (SD)	171.15 (8.830)	172.74 (6.982)	170.53 (5.963)	171.70 (6.517)	171.54 (7.159)
Median	174.00	173.00	168.00	172.00	173.00
Min, Max	155.0, 184.0	163.5, 183.0	162.0, 183.0	162.0, 183.0	155.0, 184.0
Weight (kg)					
n	13	17	15	32	45
Mean (SD)	75.36 (9.774)	75.62 (13.790)	72.66 (11.540)	74.23 (12.670)	74.56 (11.808)
Median	73.00	70.50	68.80	70.00	71.00
Min, Max	61.3, 94.0	55.5, 112.0	54.3, 91.4	54.3, 112.0	54.3, 112.0
BMI (kg/m^2)					
n	13	17	15	32	45
Mean (SD)	25.69 (2.399)	25.47 (5.167)	24.99 (3.717)	25.25 (4.481)	25.37 (3.970)
Median	25.51	23.01	24.45	23.63	24.49
Min, Max	21.8, 30.4	19.6, 37.9	17.1, 31.2	17.1, 37.9	17.1, 37.9
Any concomitant diseases, n (%)					
n	13	17	15	32	45
Yes	4 (30.8)	4 (23.5)	3 (20.0)	7 (21.9)	11 (24.4)
No	9 (69.2)	13 (76.5)	12 (80.0)	25 (78.1)	34 (75.6)
Hospitalization status at informed consent, n (%)					

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
n	13	17	15	32	45
Inpatient	13 (100.0)	16 (94.1)	13 (86.7)	29 (90.6)	42 (93.3)
Within 3 months (90 days)	13 (100.0)	16 (94.1)	13 (86.7)	29 (90.6)	42 (93.3)
Over 3 months	0	0	0	0	0
Unknown	0	0	0	0	0
Outpatient	0	1 (5.9)	2 (13.3)	3 (9.4)	3 (6.7)

The denominator of percentages is the number of subjects in analysis population of subgroup. The final data at Open-Week 52 was used.

Control No:<<t14-01-04-06-01-dm.sas, 2018-11-14T20:03:29>>

表2.7.4.7-23　日本人集団での疾患データ（20試験・ロナセンテープ貼付期、Open-52週）
DSP-5423P Dosed Population

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
Number of episodes of schizophrenia					
n	24	40	48	88	112
Mean (SD)	3.7 (1.52)	3.3 (1.43)	3.9 (1.34)	3.6 (1.41)	3.6 (1.43)
Median	4.5	3.0	5.0	4.0	4.0
Min, Max	1, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	27	55	57	112	139
1	3 (11.1)	4 (7.3)	3 (5.3)	7 (6.3)	10 (7.2)
2	3 (11.1)	11 (20.0)	6 (10.5)	17 (15.2)	20 (14.4)
3	4 (14.8)	9 (16.4)	9 (15.8)	18 (16.1)	22 (15.8)
4	2 (7.4)	3 (5.5)	5 (8.8)	8 (7.1)	10 (7.2)
5 or more	12 (44.4)	13 (23.6)	25 (43.9)	38 (33.9)	50 (36.0)
Unknown	3 (11.1)	15 (27.3)	9 (15.8)	24 (21.4)	27 (19.4)
Age at the first onset of schizophrenia (years)					
n	27	53	56	109	136
Mean (SD)	29.6 (11.28)	29.5 (12.97)	28.3 (11.87)	28.9 (12.38)	29.1 (12.13)
Median	28.0	25.0	25.0	25.0	25.5
Min, Max	12, 58	12, 67	13, 60	12, 67	12, 67
Age at the first onset of schizophrenia (years), n (%)					
n	27	55	57	112	139
19 or less	6 (22.2)	12 (21.8)	16 (28.1)	28 (25.0)	34 (24.5)
20 to 29	8 (29.6)	22 (40.0)	18 (31.6)	40 (35.7)	48 (34.5)
30 to 39	8 (29.6)	7 (12.7)	11 (19.3)	18 (16.1)	26 (18.7)
40 to 49	4 (14.8)	7 (12.7)	8 (14.0)	15 (13.4)	19 (13.7)

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
50 or more	1 (3.7)	5 (9.1)	3 (5.3)	8 (7.1)	9 (6.5)
Unknown	0	2 (3.6)	1 (1.8)	3 (2.7)	3 (2.2)
Duration of illness (years)					
n	27	53	56	109	136
Mean (SD)	21.84 (16.942)	17.97 (14.593)	19.58 (15.449)	18.79 (14.991)	19.40 (15.380)
Median	22.88	13.68	15.82	15.35	15.39
Min, Max	0.1, 47.8	0.3, 55.2	0.7, 50.6	0.3, 55.2	0.1, 55.2
Duration of illness (years), n (%)					
n	27	55	57	112	139
<1	2 (7.4)	4 (7.3)	1 (1.8)	5 (4.5)	7 (5.0)
>=1 to <5	4 (14.8)	9 (16.4)	8 (14.0)	17 (15.2)	21 (15.1)
>=5 to <10	4 (14.8)	5 (9.1)	13 (22.8)	18 (16.1)	22 (15.8)
>=10 to <20	3 (11.1)	15 (27.3)	11 (19.3)	26 (23.2)	29 (20.9)
>=20 to <30	5 (18.5)	9 (16.4)	10 (17.5)	19 (17.0)	24 (17.3)
>=30	9 (33.3)	11 (20.0)	13 (22.8)	24 (21.4)	33 (23.7)
Unknown	0	2 (3.6)	1 (1.8)	3 (2.7)	3 (2.2)
Duration of current episode (months)					
n	27	55	57	112	139
Mean (SD)	12.71 (58.388)	8.38 (46.869)	9.27 (59.028)	8.84 (53.167)	9.59 (54.021)
Median	1.18	1.35	1.15	1.22	1.22
Min, Max	0.3, 304.8	0.0, 348.9	0.2, 447.0	0.0, 447.0	0.0, 447.0
Baseline PANSS total score					
n	27	55	57	112	139
Mean (SD)	102.3 (16.99)	102.7 (16.85)	104.5 (15.45)	103.6 (16.11)	103.4 (16.23)
Median	99.0	101.0	101.0	101.0	101.0
Min, Max	80, 141	80, 157	83, 155	80, 157	80, 157

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
PANSS composite subscale at baseline, n (%)					
n	27	55	57	112	139
Positive subscale score>Negative subscale score	9 (33.3)	23 (41.8)	21 (36.8)	44 (39.3)	53 (38.1)
Positive subscale score=Negative subscale score	1 (3.7)	2 (3.6)	5 (8.8)	7 (6.3)	8 (5.8)
Positive subscale score<Negative subscale score	17 (63.0)	30 (54.5)	31 (54.4)	61 (54.5)	78 (56.1)
Baseline PANSS total score, n (%)					
n	27	55	57	112	139
<100	14 (51.9)	27 (49.1)	25 (43.9)	52 (46.4)	66 (47.5)
>=100 to <120	9 (33.3)	19 (34.5)	24 (42.1)	43 (38.4)	52 (37.4)
>=120	4 (14.8)	9 (16.4)	8 (14.0)	17 (15.2)	21 (15.1)
Baseline CGI-S score					
n	27	55	57	112	139
Mean (SD)	4.56 (0.751)	4.64 (0.825)	4.77 (0.887)	4.71 (0.856)	4.68 (0.836)
Median	4.00	4.00	5.00	5.00	4.00
Min, Max	4, 6	3, 7	3, 7	3, 7	3, 7
Baseline CGI-S score, n (%)					
n	27	55	57	112	139
1	0	0	0	0	0
2	0	0	0	0	0
3	0	1 (1.8)	1 (1.8)	2 (1.8)	2 (1.4)
4	16 (59.3)	28 (50.9)	25 (43.9)	53 (47.3)	69 (49.6)
5	7 (25.9)	17 (30.9)	19 (33.3)	36 (32.1)	43 (30.9)
6	4 (14.8)	8 (14.5)	10 (17.5)	18 (16.1)	22 (15.8)
7	0	1 (1.8)	2 (3.5)	3 (2.7)	3 (2.2)
Baseline DIEPSS total score (excluding overall severity)					

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
n	27	55	56	111	138
Mean (SD)	1.7 (2.88)	1.6 (3.00)	1.9 (3.54)	1.8 (3.27)	1.8 (3.19)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 10	0, 14	0, 14	0, 14	0, 14

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Number of episodes of schizophrenia					
n	8	9	10	19	27
Mean (SD)	3.8 (1.58)	3.6 (1.59)	2.7 (1.49)	3.1 (1.56)	3.3 (1.56)
Median	4.5	4.0	2.0	3.0	3.0
Min, Max	1, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	8	9	10	19	27
1	1 (12.5)	1 (11.1)	2 (20.0)	3 (15.8)	4 (14.8)
2	1 (12.5)	2 (22.2)	4 (40.0)	6 (31.6)	7 (25.9)
3	1 (12.5)	1 (11.1)	1 (10.0)	2 (10.5)	3 (11.1)
4	1 (12.5)	1 (11.1)	1 (10.0)	2 (10.5)	3 (11.1)
5 or more	4 (50.0)	4 (44.4)	2 (20.0)	6 (31.6)	10 (37.0)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	8	9	10	19	27
Mean (SD)	25.1 (9.30)	27.0 (7.91)	24.8 (5.83)	25.8 (6.78)	25.6 (7.43)
Median	22.5	24.0	24.5	24.0	24.0
Min, Max	11, 40	19, 43	17, 36	17, 43	11, 43
Age at the first onset of schizophrenia (years), n (%)					
n	8	9	10	19	27
19 or less	1 (12.5)	1 (11.1)	1 (10.0)	2 (10.5)	3 (11.1)
20 to 29	5 (62.5)	5 (55.6)	7 (70.0)	12 (63.2)	17 (63.0)
30 to 39	1 (12.5)	2 (22.2)	2 (20.0)	4 (21.1)	5 (18.5)
40 to 49	1 (12.5)	1 (11.1)	0	1 (5.3)	2 (7.4)
50 or more	0	0	0	0	0
Unknown	0	0	0	0	0

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Duration of illness (years)					
n	8	9	10	19	27
Mean (SD)	22.62 (17.273)	14.83 (13.837)	11.43 (11.481)	13.04 (12.411)	15.88 (14.382)
Median	28.21	8.45	6.46	8.18	8.45
Min, Max	1.1, 40.1	0.5, 42.3	1.6, 34.0	0.5, 42.3	0.5, 42.3
Duration of illness (years), n (%)					
n	8	9	10	19	27
<1	0	1 (11.1)	0	1 (5.3)	1 (3.7)
>=1 to <5	2 (25.0)	1 (11.1)	5 (50.0)	6 (31.6)	8 (29.6)
>=5 to <10	1 (12.5)	3 (33.3)	1 (10.0)	4 (21.1)	5 (18.5)
>=10 to <20	0	1 (11.1)	2 (20.0)	3 (15.8)	3 (11.1)
>=20 to <30	1 (12.5)	2 (22.2)	1 (10.0)	3 (15.8)	4 (14.8)
>=30	4 (50.0)	1 (11.1)	1 (10.0)	2 (10.5)	6 (22.2)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	8	9	10	19	27
Mean (SD)	2.93 (4.417)	12.39 (33.382)	6.58 (10.952)	9.33 (23.751)	7.44 (20.116)
Median	1.38	1.28	1.49	1.38	1.38
Min, Max	0.4, 13.7	0.4, 101.4	0.9, 33.3	0.4, 101.4	0.4, 101.4
Baseline PANSS total score					
n	8	9	10	19	27
Mean (SD)	96.0 (10.07)	97.0 (8.38)	94.8 (11.82)	95.8 (10.12)	95.9 (9.91)
Median	94.0	97.0	99.5	98.0	95.0
Min, Max	84, 117	85, 113	81, 116	81, 116	81, 117
PANSS composite subscale at baseline, n (%)					
n	8	9	10	19	27

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Positive subscale score>Negative subscale score	3 (37.5)	2 (22.2)	2 (20.0)	4 (21.1)	7 (25.9)
Positive subscale score=Negative subscale score	2 (25.0)	0	1 (10.0)	1 (5.3)	3 (11.1)
Positive subscale score<Negative subscale score	3 (37.5)	7 (77.8)	7 (70.0)	14 (73.7)	17 (63.0)
Baseline PANSS total score, n (%)					
n	8	9	10	19	27
<100	6 (75.0)	7 (77.8)	5 (50.0)	12 (63.2)	18 (66.7)
>=100 to <120	2 (25.0)	2 (22.2)	5 (50.0)	7 (36.8)	9 (33.3)
>=120	0	0	0	0	0
Baseline CGI-S score					
n	8	9	10	19	27
Mean (SD)	5.25 (0.707)	5.67 (0.707)	5.10 (0.568)	5.37 (0.684)	5.33 (0.679)
Median	5.00	6.00	5.00	5.00	5.00
Min, Max	4, 6	4, 6	4, 6	4, 6	4, 6
Baseline CGI-S score, n (%)					
n	8	9	10	19	27
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	1 (12.5)	1 (11.1)	1 (10.0)	2 (10.5)	3 (11.1)
5	4 (50.0)	1 (11.1)	7 (70.0)	8 (42.1)	12 (44.4)
6	3 (37.5)	7 (77.8)	2 (20.0)	9 (47.4)	12 (44.4)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	8	9	10	19	27
Mean (SD)	2.5 (4.78)	1.0 (1.50)	1.9 (2.81)	1.5 (2.27)	1.8 (3.15)

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Median	0.5	0.0	0.5	0.0	0.0
Min, Max	0, 14	0, 4	0, 7	0, 7	0, 14

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Number of episodes of schizophrenia					
n	3	7	7	14	17
Mean (SD)	5.0 (0.00)	3.7 (1.70)	3.7 (1.70)	3.7 (1.64)	3.9 (1.56)
Median	5.0	5.0	5.0	5.0	5.0
Min, Max	5, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	3	7	7	14	17
1	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
2	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
3	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
4	0	0	0	0	0
5 or more	3 (100.0)	4 (57.1)	4 (57.1)	8 (57.1)	11 (64.7)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	3	7	7	14	17
Mean (SD)	31.3 (6.35)	29.4 (12.18)	30.3 (8.24)	29.9 (10.00)	30.1 (9.31)
Median	35.0	27.0	28.0	28.0	28.0
Min, Max	24, 35	18, 53	21, 43	18, 53	18, 53
Age at the first onset of schizophrenia (years), n (%)					
n	3	7	7	14	17
19 or less	0	2 (28.6)	0	2 (14.3)	2 (11.8)
20 to 29	1 (33.3)	3 (42.9)	5 (71.4)	8 (57.1)	9 (52.9)
30 to 39	2 (66.7)	1 (14.3)	0	1 (7.1)	3 (17.6)
40 to 49	0	0	2 (28.6)	2 (14.3)	2 (11.8)
50 or more	0	1 (14.3)	0	1 (7.1)	1 (5.9)
Unknown	0	0	0	0	0

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Duration of illness (years)					
n	3	7	7	14	17
Mean (SD)	19.62 (7.396)	10.50 (5.780)	10.37 (9.413)	10.43 (7.505)	12.05 (8.102)
Median	17.80	10.80	8.40	10.10	10.95
Min, Max	13.3, 27.8	0.6, 17.5	0.5, 27.6	0.5, 27.6	0.5, 27.8
Duration of illness (years), n (%)					
n	3	7	7	14	17
<1	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
>=1 to <5	0	0	1 (14.3)	1 (7.1)	1 (5.9)
>=5 to <10	0	2 (28.6)	2 (28.6)	4 (28.6)	4 (23.5)
>=10 to <20	2 (66.7)	4 (57.1)	2 (28.6)	6 (42.9)	8 (47.1)
>=20 to <30	1 (33.3)	0	1 (14.3)	1 (7.1)	2 (11.8)
>=30	0	0	0	0	0
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	3	7	7	14	17
Mean (SD)	1.42 (0.294)	1.10 (0.363)	1.50 (0.675)	1.30 (0.560)	1.32 (0.518)
Median	1.58	1.05	1.77	1.36	1.38
Min, Max	1.1, 1.6	0.6, 1.6	0.3, 2.1	0.3, 2.1	0.3, 2.1
Baseline PANSS total score					
n	3	7	7	14	17
Mean (SD)	99.3 (17.39)	113.4 (17.58)	98.0 (14.55)	105.7 (17.45)	104.6 (17.07)
Median	93.0	119.0	96.0	107.0	99.0
Min, Max	86, 119	84, 133	82, 119	82, 133	82, 133
PANSS composite subscale at baseline, n (%)					
n	3	7	7	14	17

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Positive subscale score>Negative subscale score	1 (33.3)	5 (71.4)	4 (57.1)	9 (64.3)	10 (58.8)
Positive subscale score=Negative subscale score	0	0	0	0	0
Positive subscale score<Negative subscale score	2 (66.7)	2 (28.6)	3 (42.9)	5 (35.7)	7 (41.2)
Baseline PANSS total score, n (%)					
n	3	7	7	14	17
<100	2 (66.7)	2 (28.6)	5 (71.4)	7 (50.0)	9 (52.9)
>=100 to <120	1 (33.3)	2 (28.6)	2 (28.6)	4 (28.6)	5 (29.4)
>=120	0	3 (42.9)	0	3 (21.4)	3 (17.6)
Baseline CGI-S score					
n	3	7	7	14	17
Mean (SD)	4.67 (1.155)	5.43 (1.134)	4.43 (0.787)	4.93 (1.072)	4.88 (1.054)
Median	4.00	6.00	4.00	5.00	5.00
Min, Max	4, 6	3, 6	4, 6	3, 6	3, 6
Baseline CGI-S score, n (%)					
n	3	7	7	14	17
1	0	0	0	0	0
2	0	0	0	0	0
3	0	1 (14.3)	0	1 (7.1)	1 (5.9)
4	2 (66.7)	0	5 (71.4)	5 (35.7)	7 (41.2)
5	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
6	1 (33.3)	5 (71.4)	1 (14.3)	6 (42.9)	7 (41.2)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	3	7	7	14	17
Mean (SD)	5.3 (9.24)	0.0 (0.00)	1.1 (2.61)	0.6 (1.87)	1.4 (4.12)

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 16	0, 0	0, 7	0, 7	0, 16

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Number of episodes of schizophrenia					
n	43	55	54	109	152
Mean (SD)	3.4 (1.35)	3.5 (1.29)	3.5 (1.44)	3.5 (1.36)	3.5 (1.35)
Median	3.0	3.0	3.5	3.0	3.0
Min, Max	1, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	43	58	54	112	155
1	2 (4.7)	2 (3.4)	3 (5.6)	5 (4.5)	7 (4.5)
2	13 (30.2)	13 (22.4)	17 (31.5)	30 (26.8)	43 (27.7)
3	9 (20.9)	14 (24.1)	7 (13.0)	21 (18.8)	30 (19.4)
4	5 (11.6)	7 (12.1)	5 (9.3)	12 (10.7)	17 (11.0)
5 or more	14 (32.6)	19 (32.8)	22 (40.7)	41 (36.6)	55 (35.5)
Unknown	0	3 (5.2)	0	3 (2.7)	3 (1.9)
Age at the first onset of schizophrenia (years)					
n	41	56	52	108	149
Mean (SD)	28.1 (8.75)	25.3 (7.03)	25.7 (7.49)	25.5 (7.22)	26.2 (7.73)
Median	27.0	24.0	24.5	24.0	25.0
Min, Max	12, 49	15, 41	13, 55	13, 55	12, 55
Age at the first onset of schizophrenia (years), n (%)					
n	43	58	54	112	155
19 or less	7 (16.3)	11 (19.0)	9 (16.7)	20 (17.9)	27 (17.4)
20 to 29	17 (39.5)	30 (51.7)	30 (55.6)	60 (53.6)	77 (49.7)
30 to 39	14 (32.6)	13 (22.4)	11 (20.4)	24 (21.4)	38 (24.5)
40 to 49	3 (7.0)	2 (3.4)	1 (1.9)	3 (2.7)	6 (3.9)
50 or more	0	0	1 (1.9)	1 (0.9)	1 (0.6)
Unknown	2 (4.7)	2 (3.4)	2 (3.7)	4 (3.6)	6 (3.9)

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Duration of illness (years)					
n	41	56	52	108	149
Mean (SD)	12.17 (9.986)	11.39 (9.028)	9.33 (8.674)	10.40 (8.879)	10.89 (9.197)
Median	10.22	9.08	6.08	7.33	8.10
Min, Max	0.1, 40.6	0.0, 32.2	0.0, 38.6	0.0, 38.6	0.0, 40.6
Duration of illness (years), n (%)					
n	43	58	54	112	155
<1	6 (14.0)	5 (8.6)	5 (9.3)	10 (8.9)	16 (10.3)
>=1 to <5	5 (11.6)	13 (22.4)	16 (29.6)	29 (25.9)	34 (21.9)
>=5 to <10	8 (18.6)	10 (17.2)	12 (22.2)	22 (19.6)	30 (19.4)
>=10 to <20	15 (34.9)	18 (31.0)	12 (22.2)	30 (26.8)	45 (29.0)
>=20 to <30	4 (9.3)	8 (13.8)	6 (11.1)	14 (12.5)	18 (11.6)
>=30	3 (7.0)	2 (3.4)	1 (1.9)	3 (2.7)	6 (3.9)
Unknown	2 (4.7)	2 (3.4)	2 (3.7)	4 (3.6)	6 (3.9)
Duration of current episode (months)					
n	43	58	54	112	155
Mean (SD)	1.13 (0.605)	1.23 (1.719)	1.24 (0.615)	1.23 (1.303)	1.20 (1.152)
Median	1.08	0.95	1.13	1.03	1.05
Min, Max	0.2, 2.4	0.2, 13.3	0.2, 2.8	0.2, 13.3	0.2, 13.3
Baseline PANSS total score					
n	43	58	54	112	155
Mean (SD)	97.6 (13.71)	103.2 (15.90)	103.6 (17.35)	103.4 (16.54)	101.8 (15.98)
Median	93.0	101.0	100.0	101.0	100.0
Min, Max	80, 135	80, 147	82, 168	80, 168	80, 168
PANSS composite subscale at baseline, n (%)					
n	43	58	54	112	155

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Positive subscale score>Negative subscale score	26 (60.5)	38 (65.5)	23 (42.6)	61 (54.5)	87 (56.1)
Positive subscale score=Negative subscale score	2 (4.7)	3 (5.2)	2 (3.7)	5 (4.5)	7 (4.5)
Positive subscale score<Negative subscale score	15 (34.9)	17 (29.3)	29 (53.7)	46 (41.1)	61 (39.4)
Baseline PANSS total score, n (%)					
n	43	58	54	112	155
<100	25 (58.1)	25 (43.1)	27 (50.0)	52 (46.4)	77 (49.7)
>=100 to <120	16 (37.2)	23 (39.7)	18 (33.3)	41 (36.6)	57 (36.8)
>=120	2 (4.7)	10 (17.2)	9 (16.7)	19 (17.0)	21 (13.5)
Baseline CGI-S score					
n	43	58	54	112	155
Mean (SD)	4.86 (0.601)	4.91 (0.629)	5.15 (0.529)	5.03 (0.592)	4.98 (0.597)
Median	5.00	5.00	5.00	5.00	5.00
Min, Max	4, 6	4, 6	4, 6	4, 6	4, 6
Baseline CGI-S score, n (%)					
n	43	58	54	112	155
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	11 (25.6)	14 (24.1)	4 (7.4)	18 (16.1)	29 (18.7)
5	27 (62.8)	35 (60.3)	38 (70.4)	73 (65.2)	100 (64.5)
6	5 (11.6)	9 (15.5)	12 (22.2)	21 (18.8)	26 (16.8)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	43	58	54	112	155
Mean (SD)	0.2 (0.53)	0.3 (1.59)	0.1 (0.56)	0.2 (1.21)	0.2 (1.06)

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 3	0, 10	0, 3	0, 10	0, 10

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Number of episodes of schizophrenia					
n	22	22	22	44	66
Mean (SD)	3.5 (1.22)	3.7 (1.12)	4.0 (1.21)	3.8 (1.16)	3.7 (1.18)
Median	3.0	4.0	4.0	4.0	4.0
Min, Max	2, 5	2, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	22	22	22	44	66
1	0	0	1 (4.5)	1 (2.3)	1 (1.5)
2	6 (27.3)	4 (18.2)	2 (9.1)	6 (13.6)	12 (18.2)
3	6 (27.3)	5 (22.7)	4 (18.2)	9 (20.5)	15 (22.7)
4	3 (13.6)	6 (27.3)	5 (22.7)	11 (25.0)	14 (21.2)
5 or more	7 (31.8)	7 (31.8)	10 (45.5)	17 (38.6)	24 (36.4)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	22	22	22	44	66
Mean (SD)	23.7 (7.45)	23.6 (8.23)	22.4 (5.42)	23.0 (6.92)	23.2 (7.05)
Median	21.0	22.0	21.5	22.0	21.5
Min, Max	14, 41	11, 46	13, 35	11, 46	11, 46
Age at the first onset of schizophrenia (years), n (%)					
n	22	22	22	44	66
19 or less	6 (27.3)	8 (36.4)	7 (31.8)	15 (34.1)	21 (31.8)
20 to 29	12 (54.5)	8 (36.4)	12 (54.5)	20 (45.5)	32 (48.5)
30 to 39	3 (13.6)	5 (22.7)	3 (13.6)	8 (18.2)	11 (16.7)
40 to 49	1 (4.5)	1 (4.5)	0	1 (2.3)	2 (3.0)
50 or more	0	0	0	0	0
Unknown	0	0	0	0	0

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Duration of illness (years)					
n	22	22	22	44	66
Mean (SD)	9.99 (7.262)	8.90 (6.039)	10.05 (9.364)	9.48 (7.808)	9.65 (7.578)
Median	7.88	8.27	7.08	8.27	8.13
Min, Max	1.1, 23.1	2.4, 23.6	0.0, 32.4	0.0, 32.4	0.0, 32.4
Duration of illness (years), n (%)					
n	22	22	22	44	66
<1	0	0	2 (9.1)	2 (4.5)	2 (3.0)
>=1 to <5	7 (31.8)	7 (31.8)	7 (31.8)	14 (31.8)	21 (31.8)
>=5 to <10	6 (27.3)	7 (31.8)	5 (22.7)	12 (27.3)	18 (27.3)
>=10 to <20	6 (27.3)	6 (27.3)	4 (18.2)	10 (22.7)	16 (24.2)
>=20 to <30	3 (13.6)	2 (9.1)	3 (13.6)	5 (11.4)	8 (12.1)
>=30	0	0	1 (4.5)	1 (2.3)	1 (1.5)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	22	22	22	44	66
Mean (SD)	1.44 (0.585)	1.32 (0.689)	1.16 (0.637)	1.24 (0.661)	1.31 (0.639)
Median	1.36	1.23	1.10	1.15	1.22
Min, Max	0.4, 2.6	0.4, 3.0	0.4, 2.6	0.4, 3.0	0.4, 3.0
Baseline PANSS total score					
n	22	22	22	44	66
Mean (SD)	98.0 (12.04)	99.0 (15.40)	98.9 (13.12)	98.9 (14.14)	98.6 (13.39)
Median	96.0	93.5	95.0	94.0	94.0
Min, Max	81, 128	83, 138	80, 129	80, 138	80, 138
PANSS composite subscale at baseline, n (%)					
n	22	22	22	44	66

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Positive subscale score>Negative subscale score	9 (40.9)	16 (72.7)	11 (50.0)	27 (61.4)	36 (54.5)
Positive subscale score=Negative subscale score	1 (4.5)	0	2 (9.1)	2 (4.5)	3 (4.5)
Positive subscale score<Negative subscale score	12 (54.5)	6 (27.3)	9 (40.9)	15 (34.1)	27 (40.9)
Baseline PANSS total score, n (%)					
n	22	22	22	44	66
<100	12 (54.5)	15 (68.2)	14 (63.6)	29 (65.9)	41 (62.1)
>=100 to <120	8 (36.4)	4 (18.2)	6 (27.3)	10 (22.7)	18 (27.3)
>=120	2 (9.1)	3 (13.6)	2 (9.1)	5 (11.4)	7 (10.6)
Baseline CGI-S score					
n	22	22	22	44	66
Mean (SD)	4.82 (0.733)	4.82 (0.853)	4.86 (0.640)	4.84 (0.745)	4.83 (0.736)
Median	5.00	5.00	5.00	5.00	5.00
Min, Max	4, 6	4, 7	4, 6	4, 7	4, 7
Baseline CGI-S score, n (%)					
n	22	22	22	44	66
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	8 (36.4)	9 (40.9)	6 (27.3)	15 (34.1)	23 (34.8)
5	10 (45.5)	9 (40.9)	13 (59.1)	22 (50.0)	32 (48.5)
6	4 (18.2)	3 (13.6)	3 (13.6)	6 (13.6)	10 (15.2)
7	0	1 (4.5)	0	1 (2.3)	1 (1.5)
Baseline DIEPSS total score (excluding overall severity)					
n	22	22	22	44	66
Mean (SD)	0.2 (0.61)	0.0 (0.00)	0.2 (0.75)	0.1 (0.54)	0.2 (0.56)

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 2	0, 0	0, 3	0, 3	0, 3

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Number of episodes of schizophrenia					
n	10	13	12	25	35
Mean (SD)	4.5 (1.08)	4.5 (0.78)	4.7 (0.65)	4.6 (0.71)	4.6 (0.81)
Median	5.0	5.0	5.0	5.0	5.0
Min, Max	2, 5	3, 5	3, 5	3, 5	2, 5
Number of episodes of schizophrenia, n (%)					
n	10	13	12	25	35
1	0	0	0	0	0
2	1 (10.0)	0	0	0	1 (2.9)
3	1 (10.0)	2 (15.4)	1 (8.3)	3 (12.0)	4 (11.4)
4	0	2 (15.4)	2 (16.7)	4 (16.0)	4 (11.4)
5 or more	8 (80.0)	9 (69.2)	9 (75.0)	18 (72.0)	26 (74.3)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	10	13	12	25	35
Mean (SD)	23.0 (8.49)	23.2 (7.26)	27.8 (11.55)	25.4 (9.64)	24.7 (9.27)
Median	23.0	23.0	23.5	23.0	23.0
Min, Max	6, 40	8, 32	14, 50	8, 50	6, 50
Age at the first onset of schizophrenia (years), n (%)					
n	10	13	12	25	35
19 or less	2 (20.0)	3 (23.1)	2 (16.7)	5 (20.0)	7 (20.0)
20 to 29	7 (70.0)	7 (53.8)	6 (50.0)	13 (52.0)	20 (57.1)
30 to 39	0	3 (23.1)	2 (16.7)	5 (20.0)	5 (14.3)
40 to 49	1 (10.0)	0	1 (8.3)	1 (4.0)	2 (5.7)
50 or more	0	0	1 (8.3)	1 (4.0)	1 (2.9)
Unknown	0	0	0	0	0

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Duration of illness (years)					
n	10	13	12	25	35
Mean (SD)	10.61 (8.062)	16.32 (11.293)	14.82 (8.853)	15.60 (10.013)	14.17 (9.655)
Median	10.03	15.13	14.12	15.13	13.11
Min, Max	0.9, 29.1	2.4, 38.1	3.2, 28.1	2.4, 38.1	0.9, 38.1
Duration of illness (years), n (%)					
n	10	13	12	25	35
<1	2 (20.0)	0	0	0	2 (5.7)
>=1 to <5	0	3 (23.1)	1 (8.3)	4 (16.0)	4 (11.4)
>=5 to <10	3 (30.0)	1 (7.7)	4 (33.3)	5 (20.0)	8 (22.9)
>=10 to <20	4 (40.0)	4 (30.8)	3 (25.0)	7 (28.0)	11 (31.4)
>=20 to <30	1 (10.0)	3 (23.1)	4 (33.3)	7 (28.0)	8 (22.9)
>=30	0	2 (15.4)	0	2 (8.0)	2 (5.7)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	10	13	12	25	35
Mean (SD)	1.10 (0.517)	1.19 (0.627)	1.53 (0.609)	1.35 (0.629)	1.28 (0.603)
Median	1.25	1.25	1.51	1.48	1.28
Min, Max	0.2, 1.8	0.3, 2.2	0.3, 2.5	0.3, 2.5	0.2, 2.5
Baseline PANSS total score					
n	10	13	12	25	35
Mean (SD)	100.7 (10.30)	104.7 (20.89)	102.0 (12.63)	103.4 (17.12)	102.6 (15.38)
Median	97.5	99.0	104.0	101.0	99.0
Min, Max	86, 119	87, 146	85, 129	85, 146	85, 146
PANSS composite subscale at baseline, n (%)					
n	10	13	12	25	35

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Positive subscale score>Negative subscale score	6 (60.0)	6 (46.2)	6 (50.0)	12 (48.0)	18 (51.4)
Positive subscale score=Negative subscale score	1 (10.0)	1 (7.7)	1 (8.3)	2 (8.0)	3 (8.6)
Positive subscale score<Negative subscale score	3 (30.0)	6 (46.2)	5 (41.7)	11 (44.0)	14 (40.0)
Baseline PANSS total score, n (%)					
n	10	13	12	25	35
<100	6 (60.0)	8 (61.5)	4 (33.3)	12 (48.0)	18 (51.4)
>=100 to <120	4 (40.0)	2 (15.4)	7 (58.3)	9 (36.0)	13 (37.1)
>=120	0	3 (23.1)	1 (8.3)	4 (16.0)	4 (11.4)
Baseline CGI-S score					
n	10	13	12	25	35
Mean (SD)	4.60 (0.516)	4.92 (0.760)	4.67 (0.778)	4.80 (0.764)	4.74 (0.701)
Median	5.00	5.00	4.50	5.00	5.00
Min, Max	4, 5	4, 6	4, 6	4, 6	4, 6
Baseline CGI-S score, n (%)					
n	10	13	12	25	35
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	4 (40.0)	4 (30.8)	6 (50.0)	10 (40.0)	14 (40.0)
5	6 (60.0)	6 (46.2)	4 (33.3)	10 (40.0)	16 (45.7)
6	0	3 (23.1)	2 (16.7)	5 (20.0)	5 (14.3)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	10	13	12	25	35
Mean (SD)	1.1 (2.28)	1.9 (3.95)	1.3 (2.19)	1.6 (3.17)	1.5 (2.92)

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 7	0, 12	0, 7	0, 12	0, 12

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Number of episodes of schizophrenia					
n	5	15	16	31	36
Mean (SD)	2.8 (1.30)	3.1 (1.22)	3.4 (1.36)	3.2 (1.28)	3.2 (1.28)
Median	2.0	3.0	3.5	3.0	3.0
Min, Max	2, 5	2, 5	2, 5	2, 5	2, 5
Number of episodes of schizophrenia, n (%)					
n	5	15	17	32	37
1	0	0	0	0	0
2	3 (60.0)	7 (46.7)	7 (41.2)	14 (43.8)	17 (45.9)
3	1 (20.0)	3 (20.0)	1 (5.9)	4 (12.5)	5 (13.5)
4	0	2 (13.3)	3 (17.6)	5 (15.6)	5 (13.5)
5 or more	1 (20.0)	3 (20.0)	5 (29.4)	8 (25.0)	9 (24.3)
Unknown	0	0	1 (5.9)	1 (3.1)	1 (2.7)
Age at the first onset of schizophrenia (years)					
n	5	15	17	32	37
Mean (SD)	30.6 (7.27)	27.9 (4.82)	29.1 (11.23)	28.5 (8.71)	28.8 (8.47)
Median	32.0	28.0	26.0	27.0	28.0
Min, Max	18, 36	20, 37	17, 60	17, 60	17, 60
Age at the first onset of schizophrenia (years), n (%)					
n	5	15	17	32	37
19 or less	1 (20.0)	0	2 (11.8)	2 (6.3)	3 (8.1)
20 to 29	0	10 (66.7)	10 (58.8)	20 (62.5)	20 (54.1)
30 to 39	4 (80.0)	5 (33.3)	3 (17.6)	8 (25.0)	12 (32.4)
40 to 49	0	0	0	0	0
50 or more	0	0	2 (11.8)	2 (6.3)	2 (5.4)
Unknown	0	0	0	0	0

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Duration of illness (years)					
n	5	15	17	32	37
Mean (SD)	11.37 (10.101)	10.96 (7.899)	14.29 (10.022)	12.73 (9.103)	12.55 (9.106)
Median	10.01	8.00	13.11	10.23	10.09
Min, Max	0.5, 26.4	1.6, 26.6	0.3, 36.3	0.3, 36.3	0.3, 36.3
Duration of illness (years), n (%)					
n	5	15	17	32	37
<1	1 (20.0)	0	2 (11.8)	2 (6.3)	3 (8.1)
>=1 to <5	1 (20.0)	4 (26.7)	2 (11.8)	6 (18.8)	7 (18.9)
>=5 to <10	0	5 (33.3)	2 (11.8)	7 (21.9)	7 (18.9)
>=10 to <20	2 (40.0)	3 (20.0)	7 (41.2)	10 (31.3)	12 (32.4)
>=20 to <30	1 (20.0)	3 (20.0)	3 (17.6)	6 (18.8)	7 (18.9)
>=30	0	0	1 (5.9)	1 (3.1)	1 (2.7)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	5	15	17	32	37
Mean (SD)	0.83 (0.732)	0.99 (0.407)	0.83 (0.437)	0.90 (0.424)	0.90 (0.464)
Median	0.53	1.02	0.62	0.85	0.79
Min, Max	0.1, 2.0	0.1, 1.6	0.2, 1.8	0.1, 1.8	0.1, 2.0
Baseline PANSS total score					
n	5	15	17	32	37
Mean (SD)	109.8 (20.20)	91.6 (8.42)	93.4 (9.13)	92.6 (8.71)	94.9 (12.10)
Median	108.0	91.0	93.0	92.5	94.0
Min, Max	86, 138	81, 109	80, 113	80, 113	80, 138
PANSS composite subscale at baseline, n (%)					
n	5	15	17	32	37

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Positive subscale score>Negative subscale score	3 (60.0)	7 (46.7)	12 (70.6)	19 (59.4)	22 (59.5)
Positive subscale score=Negative subscale score	0	2 (13.3)	0	2 (6.3)	2 (5.4)
Positive subscale score<Negative subscale score	2 (40.0)	6 (40.0)	5 (29.4)	11 (34.4)	13 (35.1)
Baseline PANSS total score, n (%)					
n	5	15	17	32	37
<100	2 (40.0)	12 (80.0)	14 (82.4)	26 (81.3)	28 (75.7)
>=100 to <120	1 (20.0)	3 (20.0)	3 (17.6)	6 (18.8)	7 (18.9)
>=120	2 (40.0)	0	0	0	2 (5.4)
Baseline CGI-S score					
n	5	15	17	32	37
Mean (SD)	5.60 (1.140)	4.67 (0.724)	5.12 (0.928)	4.91 (0.856)	5.00 (0.913)
Median	6.00	5.00	5.00	5.00	5.00
Min, Max	4, 7	4, 6	4, 7	4, 7	4, 7
Baseline CGI-S score, n (%)					
n	5	15	17	32	37
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	1 (20.0)	7 (46.7)	5 (29.4)	12 (37.5)	13 (35.1)
5	1 (20.0)	6 (40.0)	6 (35.3)	12 (37.5)	13 (35.1)
6	2 (40.0)	2 (13.3)	5 (29.4)	7 (21.9)	9 (24.3)
7	1 (20.0)	0	1 (5.9)	1 (3.1)	2 (5.4)
Baseline DIEPSS total score (excluding overall severity)					
n	5	15	17	32	37
Mean (SD)	2.2 (4.38)	0.6 (1.12)	1.5 (2.70)	1.1 (2.12)	1.2 (2.48)

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 10	0, 4	0, 8	0, 8	0, 10

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Number of episodes of schizophrenia					
n	13	17	15	32	45
Mean (SD)	4.8 (0.60)	4.9 (0.33)	4.9 (0.26)	4.9 (0.30)	4.9 (0.40)
Median	5.0	5.0	5.0	5.0	5.0
Min, Max	3, 5	4, 5	4, 5	4, 5	3, 5
Number of episodes of schizophrenia, n (%)					
n	13	17	15	32	45
1	0	0	0	0	0
2	0	0	0	0	0
3	1 (7.7)	0	0	0	1 (2.2)
4	1 (7.7)	2 (11.8)	1 (6.7)	3 (9.4)	4 (8.9)
5 or more	11 (84.6)	15 (88.2)	14 (93.3)	29 (90.6)	40 (88.9)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	13	17	15	32	45
Mean (SD)	24.5 (6.21)	28.2 (7.70)	24.4 (9.07)	26.4 (8.45)	25.8 (7.85)
Median	22.0	26.0	25.0	25.5	25.0
Min, Max	16, 39	18, 49	8, 47	8, 49	8, 49
Age at the first onset of schizophrenia (years), n (%)					
n	13	17	15	32	45
19 or less	2 (15.4)	1 (5.9)	3 (20.0)	4 (12.5)	6 (13.3)
20 to 29	8 (61.5)	9 (52.9)	9 (60.0)	18 (56.3)	26 (57.8)
30 to 39	3 (23.1)	5 (29.4)	2 (13.3)	7 (21.9)	10 (22.2)
40 to 49	0	2 (11.8)	1 (6.7)	3 (9.4)	3 (6.7)
50 or more	0	0	0	0	0
Unknown	0	0	0	0	0

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Duration of illness (years)					
n	13	17	15	32	45
Mean (SD)	14.84 (7.360)	16.38 (9.050)	14.75 (11.610)	15.61 (10.190)	15.39 (9.384)
Median	14.52	16.11	14.11	14.61	14.52
Min, Max	5.0, 27.1	1.8, 33.1	3.1, 44.1	1.8, 44.1	1.8, 44.1
Duration of illness (years), n (%)					
n	13	17	15	32	45
<1	0	0	0	0	0
>=1 to <5	1 (7.7)	1 (5.9)	4 (26.7)	5 (15.6)	6 (13.3)
>=5 to <10	3 (23.1)	5 (29.4)	3 (20.0)	8 (25.0)	11 (24.4)
>=10 to <20	5 (38.5)	6 (35.3)	4 (26.7)	10 (31.3)	15 (33.3)
>=20 to <30	4 (30.8)	4 (23.5)	2 (13.3)	6 (18.8)	10 (22.2)
>=30	0	1 (5.9)	2 (13.3)	3 (9.4)	3 (6.7)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	13	17	15	32	45
Mean (SD)	1.34 (0.652)	0.95 (0.651)	0.96 (0.595)	0.96 (0.615)	1.07 (0.644)
Median	1.28	0.62	1.08	0.90	1.08
Min, Max	0.3, 2.5	0.2, 2.2	0.2, 2.2	0.2, 2.2	0.2, 2.5
Baseline PANSS total score					
n	13	17	15	32	45
Mean (SD)	100.8 (8.42)	100.4 (6.17)	101.2 (6.25)	100.8 (6.12)	100.8 (6.76)
Median	104.0	99.0	102.0	100.5	101.0
Min, Max	83, 115	91, 114	88, 114	88, 114	83, 115
PANSS composite subscale at baseline, n (%)					
n	13	17	15	32	45

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Positive subscale score>Negative subscale score	7 (53.8)	7 (41.2)	6 (40.0)	13 (40.6)	20 (44.4)
Positive subscale score=Negative subscale score	1 (7.7)	3 (17.6)	0	3 (9.4)	4 (8.9)
Positive subscale score<Negative subscale score	5 (38.5)	7 (41.2)	9 (60.0)	16 (50.0)	21 (46.7)
Baseline PANSS total score, n (%)					
n	13	17	15	32	45
<100	6 (46.2)	9 (52.9)	5 (33.3)	14 (43.8)	20 (44.4)
>=100 to <120	7 (53.8)	8 (47.1)	10 (66.7)	18 (56.3)	25 (55.6)
>=120	0	0	0	0	0
Baseline CGI-S score					
n	13	17	15	32	45
Mean (SD)	4.54 (0.519)	4.65 (0.606)	4.87 (0.352)	4.75 (0.508)	4.69 (0.514)
Median	5.00	5.00	5.00	5.00	5.00
Min, Max	4, 5	4, 6	4, 5	4, 6	4, 6
Baseline CGI-S score, n (%)					
n	13	17	15	32	45
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	6 (46.2)	7 (41.2)	2 (13.3)	9 (28.1)	15 (33.3)
5	7 (53.8)	9 (52.9)	13 (86.7)	22 (68.8)	29 (64.4)
6	0	1 (5.9)	0	1 (3.1)	1 (2.2)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	13	17	15	32	45
Mean (SD)	1.1 (2.06)	0.6 (1.80)	0.5 (0.99)	0.6 (1.46)	0.7 (1.64)
Median	0.0	0.0	0.0	0.0	0.0

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Min, Max	0, 7	0, 7	0, 3	0, 7	0, 7

The denominator of percentages is the number of subjects in analysis population of subgroup. Duration of illness is years from the initial episode of schizophrenia to the informed consent. Duration of current episode is months from the onset of current episode to the informed consent. In regard to 'Number of episodes of schizophrenia', a category '5 or more' is set to 5 for descriptive purpose. The final data at Open-Week 52 was used.

Control No:<<t14-01-05-06-01-ph.sas, 2018-11-14T20:03:48>>

表 2.7.4.7-24　初回発現時期別貼付中止に至った有害事象の発現割合（20 試験、二重盲検治療期）

Safety Population

System Organ Class Preferred Term	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
心臓障害					
急性心筋梗塞					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
一般・全身障害および投与部位の状態					
適用部位湿疹					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
感染症および寄生虫症					
肺炎					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
肺結核					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
傷害、中毒および処置合併症					
足関節部骨折					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
鎖骨骨折					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
肺挫傷					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
臨床検査					
血中クレアチンホスホキナーゼ増加					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190

System Organ Class Preferred Term	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
代謝および栄養障害					
食欲減退					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
神経系障害					
無動					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
ジスキネジア					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
全身性強直性間代性発作					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
ギラン・バレー症候群					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
精神運動亢進					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
精神障害					
激越					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
カタトニー					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194

System Organ Class Preferred Term	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
拒絶症					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
精神病性障害					
PLCB (N = 190)	1/190 (0.5)	1/173 (0.6)	1/155 (0.6)	0/144	3/190 (1.6)
40MG (N = 196)	2/196 (1.0)	3/179 (1.7)	1/168 (0.6)	1/155 (0.6)	7/196 (3.6)
80MG (N = 194)	0/194	2/183 (1.1)	0/175	0/169	2/194 (1.0)
統合失調症					
PLCB (N = 190)	3/190 (1.6)	4/173 (2.3)	1/155 (0.6)	3/144 (2.1)	11/190 (5.8)
40MG (N = 196)	2/196 (1.0)	2/179 (1.1)	2/168 (1.2)	0/155	6/196 (3.1)
80MG (N = 194)	1/194 (0.5)	1/183 (0.5)	0/175	0/169	2/194 (1.0)
不適切な性的行動					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
自殺念慮					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
自殺企図					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
呼吸器、胸郭および縦隔障害					
肺塞栓症					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)

TEAE = Treatment-Emergent Adverse Event; This table shows counts of subjects. If a subject experienced more than one episode of an adverse event within a preferred term (PT) or a system organ class (SOC), the subject is counted only once in the PT or the SOC for the first episode. The denominator for percentages is the number of subjects who apply study drug in the time period. TEAEs are coded by MedDRA version 19.1.

表 2.7.4.7-25　中止した被験者割合（20 試験、二重盲検治療期）

Safety Population

Relative day Discontinuted (days), n (%)	PLCB (N = 190)	40MG (N = 196)	80MG (N = 194)	Overall (N = 580)
1 to 7	13 (6.8)	12 (6.1)	3 (1.5)	28 (4.8)
8 to 14	15 (7.9)	14 (7.1)	14 (7.2)	43 (7.4)
15 to 21	11 (5.8)	6 (3.1)	3 (1.5)	20 (3.4)
22 to 28	5 (2.6)	7 (3.6)	1 (0.5)	13 (2.2)
29 to 35	4 (2.1)	7 (3.6)	6 (3.1)	17 (2.9)
36 to more	4 (2.1)	1 (0.5)	6 (3.1)	11 (1.9)
Overall	52 (27.4)	47 (24.0)	33 (17.0)	132 (22.8)

表 2.7.4.7-26　初回発現時期別有害事象の重症度別発現割合（20 試験、二重盲検治療期）

Safety Population

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
心臓障害					
急性心筋梗塞					
SEVERE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
徐脈					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
右脚ブロック					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
心筋虚血					
MODERATE					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
動悸					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
洞性頻脈					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
頻脈					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
MODERATE					

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
耳および迷路障害					
乗物酔い					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
眼障害					
眼瞼炎					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
白内障					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
複視					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
眼乾燥					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	2/194 (1.0)	1/183 (0.5)	0/175	0/169	3/194 (1.5)
涙液分泌低下					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
眼球回転発作					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
胃腸障害					
腹部不快感					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	1/168 (0.6)	0/155	2/196 (1.0)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
腹痛					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	1/175 (0.6)	1/169 (0.6)	3/194 (1.5)
下腹部痛					
MODERATE					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
上腹部痛					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
慢性胃炎					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
便秘					
MILD					
PLCB (N = 190)	1/190 (0.5)	2/173 (1.2)	0/155	2/144 (1.4)	5/190 (2.6)
40MG (N = 196)	5/196 (2.6)	2/179 (1.1)	0/168	1/155 (0.6)	8/196 (4.1)
80MG (N = 194)	3/194 (1.5)	2/183 (1.1)	1/175 (0.6)	2/169 (1.2)	8/194 (4.1)
齲歯					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
下痢					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	1/144 (0.7)	2/190 (1.1)
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	2/194 (1.0)	0/183	0/175	3/169 (1.8)	5/194 (2.6)
口内乾燥					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
消化不良					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
心窩部不快感					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
食中毒					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
胃炎					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
血便排泄					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
痔核					
MILD					

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
口腔内潰瘍形成					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
悪心					
MILD					
PLCB (N = 190)	2/190 (1.1)	1/173 (0.6)	1/155 (0.6)	0/144	4/190 (2.1)
40MG (N = 196)	1/196 (0.5)	0/179	1/168 (0.6)	1/155 (0.6)	3/196 (1.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
流涎過多					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	1/183 (0.5)	2/175 (1.1)	0/169	4/194 (2.1)
歯痛					
MILD					
PLCB (N = 190)	1/190 (0.5)	3/173 (1.7)	0/155	0/144	4/190 (2.1)
40MG (N = 196)	0/196	2/179 (1.1)	3/168 (1.8)	0/155	5/196 (2.6)
80MG (N = 194)	1/194 (0.5)	2/183 (1.1)	0/175	0/169	3/194 (1.5)
嘔吐					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	2/144 (1.4)	2/190 (1.1)
40MG (N = 196)	0/196	0/179	2/168 (1.2)	0/155	2/196 (1.0)
80MG (N = 194)	0/194	1/183 (0.5)	2/175 (1.1)	0/169	3/194 (1.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
一般・全身障害および投与部位の状態					
適用部位ざ瘡					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
適用部位皮膚炎					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	2/196 (1.0)	1/179 (0.6)	0/168	1/155 (0.6)	4/196 (2.0)
80MG (N = 194)	1/194 (0.5)	1/183 (0.5)	0/175	0/169	2/194 (1.0)
適用部位変色					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
適用部位湿疹					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
適用部位びらん					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	2/179 (1.1)	0/168	0/155	2/196 (1.0)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
適用部位紅斑					
MILD					
PLCB (N = 190)	1/190 (0.5)	1/173 (0.6)	1/155 (0.6)	0/144	3/190 (1.6)
40MG (N = 196)	6/196 (3.1)	2/179 (1.1)	1/168 (0.6)	0/155	9/196 (4.6)
80MG (N = 194)	7/194 (3.6)	4/183 (2.2)	4/175 (2.3)	2/169 (1.2)	17/194 (8.8)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	1/179 (0.6)	0/168	0/155	2/196 (1.0)
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
適用部位刺激感					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	1/194 (0.5)	1/183 (0.5)	0/175	0/169	2/194 (1.0)
適用部位そう痒感					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	2/196 (1.0)	3/179 (1.7)	4/168 (2.4)	1/155 (0.6)	10/196 (5.1)
80MG (N = 194)	7/194 (3.6)	3/183 (1.6)	1/175 (0.6)	3/169 (1.8)	14/194 (7.2)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
適用部位発疹					
MILD					
PLCB (N = 190)	0/190	2/173 (1.2)	1/155 (0.6)	0/144	3/190 (1.6)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
適用部位反応					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
適用部位小水疱					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	1/168 (0.6)	0/155	2/196 (1.0)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
無力症					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
胸部不快感					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
歩行障害					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	1/183 (0.5)	0/175	0/169	2/194 (1.0)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	1/194 (0.5)	0/183	0/175	1/169 (0.6)	2/194 (1.0)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
局所腫脹					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
倦怠感					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
末梢性浮腫					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
疼痛					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
末梢腫脹					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
MODERATE					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
発熱					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	1/169 (0.6)	2/194 (1.0)
口渇					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
肝胆道系障害					
慢性胆嚢炎					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
肝機能異常					
MILD					
PLCB (N = 190)	0/190	0/173	2/155 (1.3)	0/144	2/190 (1.1)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
肝障害					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
免疫系障害					
食物アレルギー					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
季節性アレルギー					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
感染症および寄生虫症					
適用部位感染					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
体部白癬					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
細気管支炎					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
蜂巣炎					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
結膜炎					
MILD					
PLCB (N = 190)	0/190	0/173	2/155 (1.3)	0/144	2/190 (1.1)
40MG (N = 196)	1/196 (0.5)	0/179	1/168 (0.6)	0/155	2/196 (1.0)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
膀胱炎					
MODERATE					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
爪の皮膚糸状菌症					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
毛包炎					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
皮膚真菌感染					
MILD					
PLCB (N = 190)	2/190 (1.1)	0/173	0/155	0/144	2/190 (1.1)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
胃腸炎					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
歯肉炎					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
B型肝炎					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
麦粒腫					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
インフルエンザ					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
口唇感染					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
鼻咽頭炎					
MILD					
PLCB (N = 190)	1/190 (0.5)	1/173 (0.6)	2/155 (1.3)	3/144 (2.1)	7/190 (3.7)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
40MG (N = 196)	3/196 (1.5)	0/179	1/168 (0.6)	0/155	4/196 (2.0)
80MG (N = 194)	3/194 (1.5)	0/183	3/175 (1.7)	3/169 (1.8)	9/194 (4.6)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
外耳炎					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
爪囲炎					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
咽頭炎					
MODERATE					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
肺炎					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	2/194 (1.0)	0/183	0/175	0/169	2/194 (1.0)
肺結核					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
ウイルス性気道感染					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
副鼻腔炎					
MILD					

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
皮下組織膿瘍					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
白癬感染					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
足部白癬					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
上気道感染					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	2/196 (1.0)	1/179 (0.6)	1/168 (0.6)	0/155	4/196 (2.0)
80MG (N = 194)	1/194 (0.5)	0/183	1/175 (0.6)	0/169	2/194 (1.0)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
尿路感染					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
傷害、中毒および処置合併症					
足関節部骨折					
MODERATE					

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
節足動物咬傷					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
鎖骨骨折					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
挫傷					
MILD					
PLCB (N = 190)	0/190	0/173	2/155 (1.3)	0/144	2/190 (1.1)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
耳擦過傷					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
経口曝露					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
上腕骨骨折					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
裂傷					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
靱帯捻挫					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
四肢損傷					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
口唇損傷					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
肺挫傷					
SEVERE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
引っかき傷					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
皮膚擦過傷					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	2/179 (1.1)	1/168 (0.6)	0/155	3/196 (1.5)
80MG (N = 194)	1/194 (0.5)	1/183 (0.5)	0/175	0/169	2/194 (1.0)
軟部組織損傷					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
熱傷					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
外傷性血腫					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
臨床検査					
アラニンアミノトランスフェラーゼ増加					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	1/168 (0.6)	0/155	2/196 (1.0)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	1/169 (0.6)	2/194 (1.0)
アスパラギン酸アミノトランスフェラーゼ増加					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
血中アルカリホスファターゼ増加					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
血中ビリルビン増加					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
血中コレステロール増加					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
血中クレアチンホスホキナーゼ増加					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	1/155 (0.6)	0/144	2/190 (1.1)
40MG (N = 196)	2/196 (1.0)	1/179 (0.6)	0/168	0/155	3/196 (1.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	1/175 (0.6)	0/169	2/194 (1.0)
血中クレアチニン増加					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
拡張期血圧上昇					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
血圧上昇					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
心電図ＳＴ部分下降					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
心電図Ｔ波増高					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
γ－グルタミルトランスフェラーゼ増加					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
肝酵素異常					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
肝酵素上昇					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
血小板数減少					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
尿中蛋白陽性					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
トランスアミナーゼ上昇					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
体重減少					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	1/144 (0.7)	2/190 (1.1)
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
体重増加					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	3/144 (2.1)	4/190 (2.1)
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	2/168 (1.2)	0/155	2/196 (1.0)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
白血球数減少					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
代謝および栄養障害					
食欲減退					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	1/168 (0.6)	0/155	2/196 (1.0)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
糖尿病					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
高コレステロール血症					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
高血糖					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
低カリウム血症					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	2/175 (1.1)	0/169	2/194 (1.0)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
低ナトリウム血症					
MODERATE					

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
食欲亢進					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
多飲症					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
筋骨格系および結合組織障害					
関節痛					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
背部痛					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	1/155 (0.6)	0/144	2/190 (1.1)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
筋固縮					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	1/183 (0.5)	2/175 (1.1)	1/169 (0.6)	4/194 (2.1)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	1/155 (0.6)	2/196 (1.0)
80MG (N = 194)	2/194 (1.0)	0/183	1/175 (0.6)	0/169	3/194 (1.5)
筋骨格系胸痛					
MILD					

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
筋骨格硬直					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
筋肉痛					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
四肢痛					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
神経系障害					
アカシジア					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	1/155 (0.6)	0/144	2/190 (1.1)
40MG (N = 196)	2/196 (1.0)	0/179	2/168 (1.2)	5/155 (3.2)	9/196 (4.6)
80MG (N = 194)	3/194 (1.5)	6/183 (3.3)	2/175 (1.1)	2/169 (1.2)	13/194 (6.7)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	1/155 (0.6)	2/196 (1.0)
80MG (N = 194)	2/194 (1.0)	1/183 (0.5)	2/175 (1.1)	0/169	5/194 (2.6)
SEVERE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
無動					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
自律神経失調					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
運動緩慢					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	1/183 (0.5)	1/175 (0.6)	1/169 (0.6)	3/194 (1.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	1/183 (0.5)	0/175	1/169 (0.6)	3/194 (1.5)
大脳萎縮					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
浮動性めまい					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	1/144 (0.7)	2/190 (1.1)
40MG (N = 196)	0/196	0/179	2/168 (1.2)	0/155	2/196 (1.0)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
体位性めまい					
MODERATE					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
構語障害					

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
ジスキネジア					
MILD					
PLCB (N = 190)	0/190	0/173	2/155 (1.3)	1/144 (0.7)	3/190 (1.6)
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	1/194 (0.5)	2/183 (1.1)	1/175 (0.6)	1/169 (0.6)	5/194 (2.6)
ジストニア					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
全身性強直性間代性発作					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
SEVERE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
ギラン・バレー症候群					
SEVERE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
頭痛					
MILD					
PLCB (N = 190)	1/190 (0.5)	1/173 (0.6)	2/155 (1.3)	0/144	4/190 (2.1)
40MG (N = 196)	3/196 (1.5)	4/179 (2.2)	2/168 (1.2)	0/155	9/196 (4.6)
80MG (N = 194)	0/194	1/183 (0.5)	2/175 (1.1)	4/169 (2.4)	7/194 (3.6)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
過眠症					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
筋緊張亢進					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
感覚鈍麻					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
意識消失					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
パーキンソン歩行					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	2/175 (1.1)	0/169	2/194 (1.0)
睡眠の質低下					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
精神運動亢進					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
SEVERE					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
表情減少					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
傾眠					
MILD					
PLCB (N = 190)	3/190 (1.6)	0/173	1/155 (0.6)	1/144 (0.7)	5/190 (2.6)
40MG (N = 196)	0/196	1/179 (0.6)	0/168	1/155 (0.6)	2/196 (1.0)
80MG (N = 194)	1/194 (0.5)	0/183	1/175 (0.6)	0/169	2/194 (1.0)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
失神					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
振戦					
MILD					
PLCB (N = 190)	1/190 (0.5)	2/173 (1.2)	1/155 (0.6)	0/144	4/190 (2.1)
40MG (N = 196)	2/196 (1.0)	1/179 (0.6)	3/168 (1.8)	2/155 (1.3)	8/196 (4.1)
80MG (N = 194)	4/194 (2.1)	4/183 (2.2)	5/175 (2.9)	3/169 (1.8)	16/194 (8.2)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
精神障害					
攻撃性					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	2/196 (1.0)	0/179	1/168 (0.6)	0/155	3/196 (1.5)
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
激越					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	1/155 (0.6)	0/144	2/190 (1.1)
40MG (N = 196)	2/196 (1.0)	0/179	3/168 (1.8)	1/155 (0.6)	6/196 (3.1)
80MG (N = 194)	1/194 (0.5)	1/183 (0.5)	1/175 (0.6)	2/169 (1.2)	5/194 (2.6)
MODERATE					
PLCB (N = 190)	1/190 (0.5)	1/173 (0.6)	2/155 (1.3)	1/144 (0.7)	5/190 (2.6)
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
不安					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	2/179 (1.1)	0/168	0/155	2/196 (1.0)
80MG (N = 194)	1/194 (0.5)	0/183	0/175	3/169 (1.8)	4/194 (2.1)
カタトニー					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
SEVERE					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
妄想					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
幻聴					
MODERATE					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
幻視					
MILD					

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
敵意					
MODERATE					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
衝動行為					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
不眠症					
MILD					
PLCB (N = 190)	4/190 (2.1)	1/173 (0.6)	2/155 (1.3)	1/144 (0.7)	8/190 (4.2)
40MG (N = 196)	2/196 (1.0)	1/179 (0.6)	3/168 (1.8)	2/155 (1.3)	8/196 (4.1)
80MG (N = 194)	2/194 (1.0)	3/183 (1.6)	1/175 (0.6)	0/169	6/194 (3.1)
MODERATE					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	1/179 (0.6)	1/168 (0.6)	0/155	2/196 (1.0)
80MG (N = 194)	1/194 (0.5)	1/183 (0.5)	1/175 (0.6)	1/169 (0.6)	4/194 (2.1)
故意の自傷行為					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
易刺激性					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	1/169 (0.6)	2/194 (1.0)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
拒絶症					
SEVERE					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
精神症状					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
心因性呼吸窮迫					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
精神病的行動					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
精神病性障害					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
MODERATE					
PLCB (N = 190)	2/190 (1.1)	1/173 (0.6)	1/155 (0.6)	0/144	4/190 (2.1)
40MG (N = 196)	3/196 (1.5)	2/179 (1.1)	1/168 (0.6)	0/155	6/196 (3.1)
80MG (N = 194)	0/194	2/183 (1.1)	1/175 (0.6)	0/169	3/194 (1.5)
SEVERE					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	1/179 (0.6)	0/168	1/155 (0.6)	2/196 (1.0)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
落ち着きのなさ					
MILD					

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
PLCB (N = 190)	0/190	1/173 (0.6)	1/155 (0.6)	1/144 (0.7)	3/190 (1.6)
40MG (N = 196)	1/196 (0.5)	0/179	0/168	1/155 (0.6)	2/196 (1.0)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
MODERATE					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
統合失調症					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
MODERATE					
PLCB (N = 190)	2/190 (1.1)	2/173 (1.2)	2/155 (1.3)	2/144 (1.4)	8/190 (4.2)
40MG (N = 196)	3/196 (1.5)	0/179	1/168 (0.6)	1/155 (0.6)	5/196 (2.6)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
SEVERE					
PLCB (N = 190)	1/190 (0.5)	2/173 (1.2)	1/155 (0.6)	1/144 (0.7)	5/190 (2.6)
40MG (N = 196)	0/196	2/179 (1.1)	2/168 (1.2)	0/155	4/196 (2.0)
80MG (N = 194)	1/194 (0.5)	1/183 (0.5)	0/175	1/169 (0.6)	3/194 (1.5)
不適切な性的行動					
SEVERE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
睡眠障害					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
自殺念慮					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
自殺企図					

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
SEVERE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
腎および尿路障害					
排尿困難					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	1/175 (0.6)	0/169	2/194 (1.0)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
失禁					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
頻尿					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
腹圧性尿失禁					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
生殖系および乳房障害					
月経困難症					
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
陰部そう痒症					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	0/179	0/168	0/155	1/196 (0.5)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
呼吸器、胸郭および縦隔障害					
息詰まり					
SEVERE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
咳嗽					
MILD					
PLCB (N = 190)	0/190	2/173 (1.2)	0/155	0/144	2/190 (1.1)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	2/175 (1.1)	1/169 (0.6)	4/194 (2.1)
呼吸困難					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
口腔咽頭痛					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
肺塞栓症					
SEVERE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
鼻漏					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
皮膚および皮下組織障害					
皮膚嚢腫					

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
皮膚炎					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	1/196 (0.5)	1/179 (0.6)	0/168	0/155	2/196 (1.0)
80MG (N = 194)	0/194	0/183	2/175 (1.1)	0/169	2/194 (1.0)
アレルギー性皮膚炎					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
皮膚乾燥					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	1/194 (0.5)	0/183	0/175	2/169 (1.2)	3/194 (1.5)
湿疹					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	1/196 (0.5)	0/179	2/168 (1.2)	0/155	3/196 (1.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
皮脂欠乏性湿疹					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	1/194 (0.5)	0/183	0/175	0/169	1/194 (0.5)
紅斑					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
嵌入爪					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
80MG (N = 194)	0/194	0/183	0/175	1/169 (0.6)	1/194 (0.5)
間擦疹					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
汗疹					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	1/144 (0.7)	1/190 (0.5)
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
そう痒症					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	1/179 (0.6)	2/168 (1.2)	0/155	3/196 (1.5)
80MG (N = 194)	0/194	3/183 (1.6)	1/175 (0.6)	0/169	4/194 (2.1)
MODERATE					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
全身性そう痒症					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
乾癬					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	1/179 (0.6)	0/168	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
発疹					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	1/155 (0.6)	0/144	2/190 (1.1)
40MG (N = 196)	1/196 (0.5)	1/179 (0.6)	0/168	0/155	2/196 (1.0)
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
斑状丘疹状皮疹					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
脂漏性皮膚炎					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
皮膚亀裂					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
皮膚病変					
MILD					
PLCB (N = 190)	0/190	1/173 (0.6)	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
社会環境					
社会的入院					
MILD					
PLCB (N = 190)	0/190	0/173	1/155 (0.6)	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
血管障害					
動脈硬化症					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	1/168 (0.6)	0/155	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
本態性高血圧症					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194

System Organ Class Preferred Term Serious	Day 1 to 7 n/m (%)	Day 8 to 14 n/m (%)	Day 15 to 28 n/m (%)	Day 29 to 42 n/m (%)	Day 1 to 42 n/m (%)
血腫					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
高血圧					
MILD					
PLCB (N = 190)	0/190	0/173	2/155 (1.3)	1/144 (0.7)	3/190 (1.6)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
MODERATE					
PLCB (N = 190)	0/190	0/173	2/155 (1.3)	0/144	2/190 (1.1)
40MG (N = 196)	1/196 (0.5)	0/179	0/168	1/155 (0.6)	2/196 (1.0)
80MG (N = 194)	0/194	0/183	1/175 (0.6)	0/169	1/194 (0.5)
高血圧クリーゼ					
MILD					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	1/155 (0.6)	1/196 (0.5)
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
低血圧					
MILD					
PLCB (N = 190)	1/190 (0.5)	0/173	0/155	0/144	1/190 (0.5)
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	0/183	0/175	0/169	0/194
MODERATE					
PLCB (N = 190)	0/190	0/173	0/155	0/144	0/190
40MG (N = 196)	0/196	0/179	0/168	0/155	0/196
80MG (N = 194)	0/194	1/183 (0.5)	0/175	0/169	1/194 (0.5)

TEAE = Treatment-Emergent Adverse Event; This table shows counts of subjects. If a subject experienced more than one episode of an adverse event within a preferred term (PT) or a system organ class (SOC), the subject is counted only once in the PT or the SOC for the first episode. The denominator for percentages is the number of subjects who apply study drug in the time period. TEAEs are coded by MedDRA version 19.1.

表 2.7.4.7-27　ロナセンテープの貼付量変更推移（40 試験）

Safety Population

Initial DSP-5423P dose in DSP-5423P Treatment Phase	Cohort 1 40 mg/day (N = 57) n (%)	60 mg/day (N = 14) n (%)	80 mg/day (N = 26) n (%)	Cohort 2 40 mg/day (N = 103) n (%)
Daily dose (mg/day)				
Week 1				
m	54	13	23	101
40 mg/day	52 (96.3)	0	0	59 (58.4)
60 mg/day	2 (3.7)	11 (84.6)	0	41 (40.6)
80 mg/day	0	2 (15.4)	23 (100.0)	1 (1.0)
Week 2				
m	51	13	22	98
40 mg/day	48 (94.1)	3 (23.1)	0	51 (52.0)
60 mg/day	2 (3.9)	10 (76.9)	0	23 (23.5)
80 mg/day	1 (2.0)	2 (15.4)	22 (100.0)	29 (29.6)
Week 4				
m	48	11	21	95
40 mg/day	43 (89.6)	2 (18.2)	0	47 (49.5)
60 mg/day	4 (8.3)	8 (72.7)	0	21 (22.1)
80 mg/day	1 (2.1)	1 (9.1)	21 (100.0)	28 (29.5)
Week 6				
m	48	10	20	92
40 mg/day	43 (89.6)	2 (20.0)	0	45 (48.9)
60 mg/day	3 (6.3)	7 (70.0)	0	18 (19.6)
80 mg/day	2 (4.2)	1 (10.0)	20 (100.0)	29 (31.5)

m is a denominator of percentage.

同一 Week 内で用量変更を行った被験者は、変更前後の両用量にカウントした。